

**Manuscript version: Published Version**

The version presented in WRAP is the published version (Version of Record).

**Persistent WRAP URL:**

<http://wrap.warwick.ac.uk/145633>

**How to cite:**

The repository item page linked to above, will contain details on accessing citation guidance from the publisher.

**Copyright and reuse:**

The Warwick Research Archive Portal (WRAP) makes this work by researchers of the University of Warwick available open access under the following conditions.

Copyright © and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable the material made available in WRAP has been checked for eligibility before being made available.

Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

**Publisher's statement:**

Please refer to the repository item page, publisher's statement section, for further information.

For more information, please contact the WRAP Team at: [wrap@warwick.ac.uk](mailto:wrap@warwick.ac.uk)



---

# CHESS PROCESS EVALUATION RESULTS REPORT

---

Version 1



Authors:

D R Ellard, V Nichols, S J C Taylor & F Griffiths

DECEMBER 1, 2020

UNIVERSITY OF WARWICK  
Warwick Clinical Trials Unit (WCTU)

## Executive Summary

**Purpose:** The purpose of this report is to present the findings from the CHES trial process evaluation. These results are being presented to the CHES Chief Investigator and the CHES team before the main trial outcomes are presented. These results will form the basis of the process evaluation interpretation of the CHES outcome as well as a process evaluation paper.

**Background:** This process evaluation is for the Chronic Headache Education and Self-management Study (CHES) RCT, which is evaluating an education and self-management group behavioural intervention for people with chronic headache. Chronic headache is defined as headaches which are present for 15 or more days per month. The most common types are chronic migraine and chronic tension type and medication overuse headaches.

**Methods:** Our process evaluation was guided by the MRC framework and explored components proposed by Steckler and Linnan including Context, Reach, Recruitment, Dose delivered, Dose received, intervention fidelity and Implementation. We employed a mixed methods approach. Using both quantitative and qualitative data. Quantitatively we explored: Reach/context, recruitment, dose delivered, dose received and fidelity. In addition to this we included the experiences of both participants and intervention facilitators about their involvement in the trial. By bringing together both the qualitative and quantitative results where we explored both early implementation (4-months) and implementation overall; looking for facilitators and barriers.

**Results:** Reach/Context results show that we reached a diverse population that was representative of national averages in terms of ethnic mix and levels of deprivation, with a good mix of rural and suburban areas. Recruitment proved to be consistent across the study with an average of 2% (31,020) of the populations from the 164 GP practices being identified as potential participants. The study team struggled to recruit all headache types and the study became predominantly populated with those reporting migraine. The research team identified 31,020 people from GP searches and contacted, of these 7% (2178) were interested in CHES, but of these only 47% (1034) were eligible, 68% (706) were randomised. There is a slight trend towards better recruitment and randomisation in less deprived areas. The study team successfully delivered 42 (2-day) group sessions. A total of 380 participants were invited to attend the two-day group sessions and the 1-2-1 discussions with a nurse. 288 (76%) attended at least part of the two-day course. 92 (24%) were not exposed to the CHES intervention at all. Of the 288 who did attend the group sessions 227 (79%) attended both days whilst 61 (21%) only attended day one. Of the 288 who took part in groups 261 (91%) had a one-to-one interaction with the nurse. Overall 380/261 (69%) achieved the predefined minimum dose (attended at least some of the course and the 1-2-1 discussion with the nurse). Only 217 (57%) fully adhered to the intervention. In terms of fidelity the intervention was delivered well with adherence being slightly better than competence. (Adherence 0.83% (0.67, 1.00) Competence 70% (0.50, 0.90)).

Interviews with participants gave us an insight into the lives of people who live with chronic headache. 31 participated in the interview study covering both the intervention and control arms. Participants provided their thoughts and feelings about the interventions, both control and active, with generally favourable comments. A sample of participants (n = 117) who were in the intervention arm provided detailed feedback on the 2-day group session and the nurse 1-2-1. Results were generally positive with high levels of satisfaction with the course overall and the facilitators. Venues, relaxation and taster sessions and the mindfulness received less favourable satisfaction scores.

Interviewees were largely positive about the group sessions with them generally liking the group format, however some sessions were more popular than others. For example, the lifestyle session, stress and anxiety and sleep sessions and overall felt it were useful to raise awareness of how these may affect headaches. Whilst the Mindfulness and relaxation for headaches Taster activity and the managing setbacks session were not well liked. Comments on the 1-2-1 sessions again were generally positive. Focus groups with the facilitators offered provided views from their perspective.

Fourteen interviewees contributed to a longitudinal examination of their experiences of the trial and its impact on their lives with chronic headache. These showed similarities and differences between the intervention and control arm participants. Again these interviews highlight the complexity of living with chronic headache. In the intervention arm participants described having made, or making, changes to their lives and headache management that could be attributed to CHES. But equally there is evidence of similar improvements in control participants.

**Conclusion:** The results of the PE, reveal that the CHES study was well conducted and it reached out to a diverse population across different geographical settings. Recruitment was successful. However, the PE does highlight that this is a complex population that may be hard to reach. The intervention components (2-day course and 1-2-1 sessions) were delivered with fidelity and, in most cases, were well received. We have results that will help interpret the outcome results from the main trial and we are making a number of recommendations.

## Contents

Executive Summary .....	1
Purpose of this report .....	6
Background .....	6
Aims .....	6
Objectives .....	6
Methods .....	7
Results .....	9
Context and Reach .....	9
Recruitment .....	11
Expression of Interest forms .....	12
Dose Delivered .....	13
Dose Received .....	14
Two-day intervention courses .....	14
One-to-nurse appointments .....	14
Adherence .....	14
Reasons given for being unable to attend .....	14
Experiences of participating in the trial .....	15
Intervention delivery staff focus groups .....	15
All facilitators .....	15
Nurse facilitators .....	18
Participant Interviews: .....	19
Participant characteristics .....	19
CHES participant interviews .....	20
1) Usual care and Relaxation Arm interview analysis .....	21
2) About the group intervention 4ms post randomisation .....	22
3) Changes attributed to participating in the intervention arm of CHES reported after the 12 month questionnaire .....	32
4) 'Headaches over time' Vignettes at baseline, 4ms and 12ms .....	34
5) CHES Phone App data from interviews (post 4m questionnaire) .....	37
Participant feedback (forms completed after the 2-day sessions) .....	37
Fidelity .....	39
Two-day intervention courses .....	39
Adherence .....	40
Competence .....	40
Inter-rater reliability .....	40

One-to-one sessions .....	40
Summary .....	41
Implementation .....	41
Reach & Context .....	41
Recruitment .....	41
Dose Delivered .....	41
Dose Received .....	41
Early implementation.....	41
Experiences of participating in the trial.....	41
Fidelity.....	42
Implementation .....	43
What are the barriers and facilitators to trial implementation? .....	43
Mechanisms of Impact.....	43
Effectiveness .....	43
Future.....	44
Limitations .....	44
Recommendations .....	45
REFERENCES .....	46
APPENDIX.....	47
Appendix 1. Reasons provided for non attendances at group sessions and nurse one-to-one sessions....	47
Appendix 2. Usual care and Relaxation Arm interview analysis .....	48
Appendix 3. Table of control component data .....	51
Appendix 4. About the group intervention 4ms post randomisation. ....	59
Appendix 5. Changes attributed to participating in the intervention arm of CHES reported after the 12 month questionnaire. ....	63

## Table of contents (Tables, Figures and Boxes)

### Tables

Table 1. Outlining process evaluation (PE) components, sources and type of data. ....	7
Table 2. GP practices included in the CHES study grouped by clinical commissioning group (CCG). ....	9
Table 3. The CHES GP practices grouped by CCG showing the percentage ethnic mix in each compared to national figures for England and Wales (Nationally 80.5% identify as White British, 4.4% other white ethnic group).....	10
Table 4. CHES recruiting GP practices grouped by index of multiple deprivation deciles .....	11
Table 5. Reasons not interested in participating in the CHES trial .....	12
Table 6. Areas in the UK where CHES groups were delivered. ....	13
Table 7. Feedback on specific CHES sessions from those delivering the intervention .....	16
Table 8. Baseline characteristics of participants interviewed compared against the overall trial population. ....	19
Table 9. Interview sample and timelines .....	20
Table 10. Interviewee responses to questions about specific sessions within the two day programme. ....	25
Table 11. Headaches over time' Vignettes at baseline, 4ms and 12ms (Control participants) .....	35
Table 12. Headaches over time' Vignettes at baseline, 4ms and 12ms (intervention participants) .....	36
Table 13. Results from CHES feedback form satisfaction questions.....	37
Table 14. Feedback responses from GP practices who participated in the CHES trial .....	39
Table 15. Adherence and competence scores .....	40

### Figures

Figure 1. The CHES process evaluation. The process evaluation components are highlighted in the shaded boxes. Informed by the intervention description which informs interpretation of outcome (adapted from Moore et al., [11]) .....	8
Figure 2. Chart showing percentages of potential participants who were interested and from these those who were eligible and randomised.....	12
Figure 3. Intervention participant allocation flow diagram .....	14

### Boxes

Box 1. Topic guide for discussions with staff. ....	15
---	----

## Purpose of this report

The purpose of this report is to present the findings and recommendations from the process evaluation undertaken on the CHES randomised controlled trial (RCT). It is important to note that there is no discussion of findings within this report this is just a presentation of results. Discussion will be included in the study monograph and the PE publication. This report will be placed within an open access database and will as such form the basis of both the PE publication and the PE chapters of study monograph

## Background

Chronic headache is defined as one which is present for 15 or more days per month for 3 months.[1] It affects between 3-4% of the population.[2] Between a quarter and a half of those affected may also have medication overuse headache (medication overuse being both a consequence of, and a cause of, chronic headache). Despite the scale of the disability associated with chronic headache worldwide,[3] there have been very few studies exploring how to support people to manage their headaches better. The Chronic HEadache and Self-management Study (CHES) study is testing the impact of a supportive self-management on the headache related quality of life in people living with chronic headaches.

Health research interventions like the CHES trial are becoming increasingly complex, encompassing many interconnecting and interacting components.[4] The primary outcome is the main focus of randomised controlled trials of complex interventions in health care. Nevertheless, consideration of the study processes, including design and execution, can be equally important. Evaluation of the principal processes of a complex study assists in elucidating why a particular intervention is, or is not, successful in achieving its outcome. It may also help to explain how an intervention could be optimised or why it may have failed.[5] There is now a growing body of published process evaluations that help to put trial results into context.[6-10] Having a clear understanding of the processes of a study is also very helpful for study replication and for informing future research.

Key components of process evaluation including; reach, recruitment, treatment fidelity, dose delivered, dose received, help to define the extent to which an intervention is implemented guided by the MRC framework.[11, 12] This structured process helps to identify problems and factors that may have caused a deviation in expected outcomes, for example it may highlight contextual factors which could have impacted the trial implementation, which might not otherwise have become apparent.

Below we will outline the aims, objectives and methods used for the process evaluation undertaken during the CHES trial. Full details of the rationale, background and methods of this process evaluation are given in the protocol paper.[13]

## Aims

The aims of the process evaluation are:

1. To assist in the interpretation of the results of the main effectiveness trial
2. To develop a set of transferable principles regarding the intervention to inform its implementation on a wider scale, if the intervention proves effective.

## Objectives

Our specific objectives are:

- To monitor implementation processes, i.e. recruitment, reach, dose delivered, dose received, delivery of the intervention and acceptability/use of the intervention in practice and fidelity
- To explore participants' experiences of living with chronic headaches whilst taking part in the trial



- To explore any ongoing use and experience of the intervention through in-depth longitudinal interviews
- To explore with members of the recruitment team and the intervention delivery teams their experiences and possible facilitators and barriers to wider implementation

## Methods

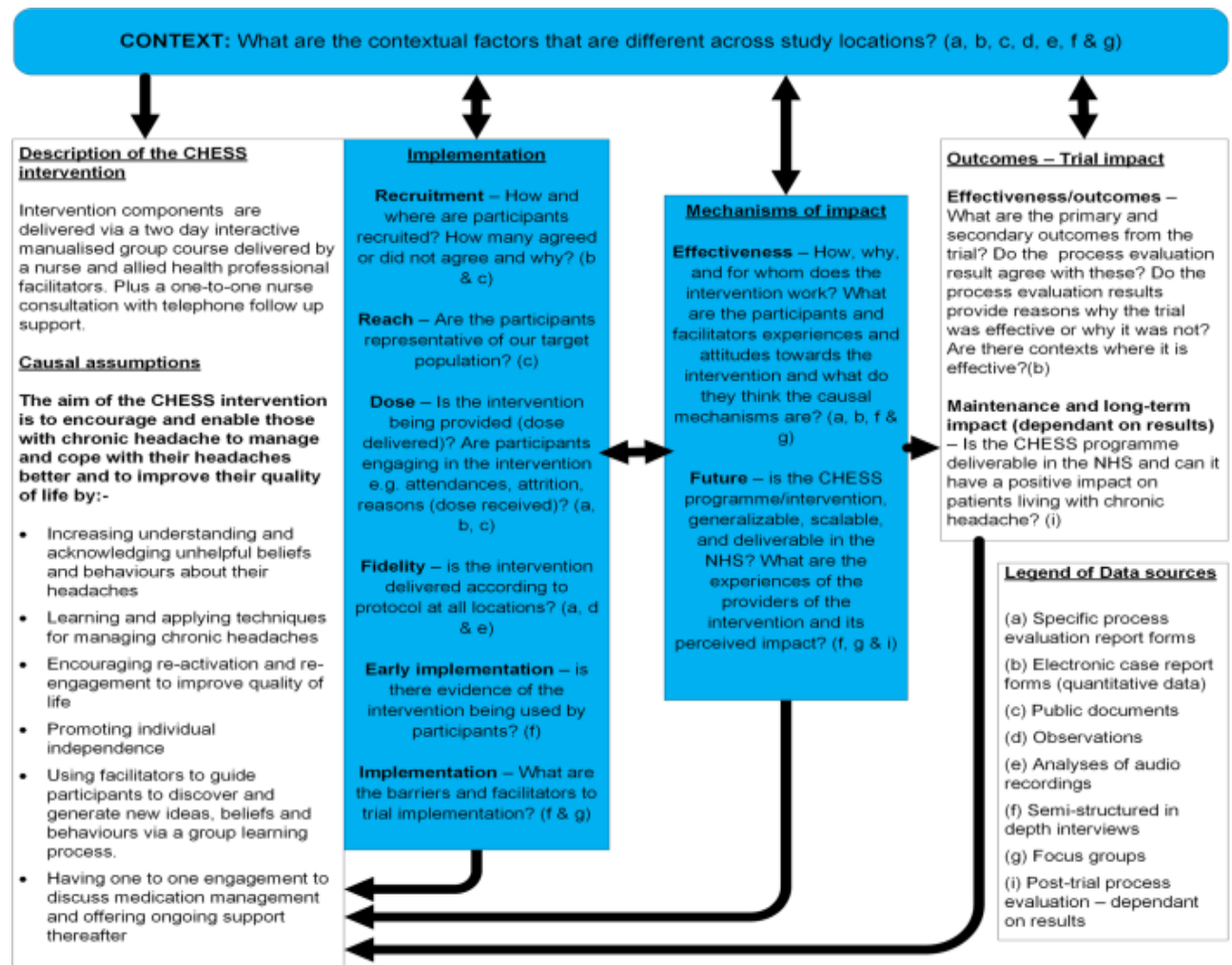
As noted a full account of the methods used can be found in our CHES process evaluation protocol paper.[13] The process evaluation was guided by the MRC framework and included key components of process evaluation proposed by Steckler and Linnan.[11, 12] Briefly we employed a mixed methods approach including quantitative and qualitative data. Table 1, below, outlines the seven core components of process evaluation which were explored in the CHES trial. Context, Reach, Recruitment, Dose-delivered, Dose received, fidelity, experiences of involvement in the trial. The table also shows our expected sources and types of data for each component.

Table 1. Outlining process evaluation (PE) components, sources and type of data.

Key PE components	Potential source of data	Type of data
<b>Reach and Context</b>	NHS GP practice data and Trial data	Practice numbers and location. Demographic and socioeconomic characteristics of population served by the practice
<b>Recruitment</b>	Trial recruitment data	Routine trial data e.g. numbers recruited, number declined, eligible. Sample of expression of interest forms from those who declined to participate
<b>Dose delivered</b>	Trial intervention data	Numbers of groups delivered/not delivered and why, location of groups
<b>Dose received</b>	Trial intervention attendance sheets Trial data Trial data	Attendance data  Telephone call uptake Reasons given for not attending
<b>Experience of participating in the trial</b>	Staff interview/focus groups Participant interviews Participant feedback forms GP feedback forms	Intervention staff focus group notes and recordings  Patient interview recordings / transcripts Participant feedback  GP feedback
<b>Fidelity</b>	Intervention group audio recordings Participants one to one consultation form completion	Audio recordings data  10% form completion check for adherence

Figure 1 below represents the logic model we have used in order to carry out this process evaluation. This shows how the multiple components are interconnected. Steckler and Linnan define implementation as an overall 'scoring' of the process evaluation components. We however, are not 'scoring' these components rather the data both qualitative and quantitative feed into them as demonstrated in the figure below. We are reporting implementation as a whole and early implementation (at around 4-months).

Figure 1. The CHES process evaluation. The process evaluation components are highlighted in the shaded boxes. Informed by the intervention description which informs interpretation of outcome (adapted from Moore et al., [11])



The results section below presents the results from the CHES RCT process evaluation they are presented against the predefined components of PE as outlined in Table 1 and Figure 1 above.

## Results

### Context and Reach

In looking at the context and reach of the CHES trial we looked closely at the areas we recruited from in terms of levels of deprivation and ethnic mix.

A total of 164 general practices (GP) in England were included in the study with a total patient population of 1,523,686 the median practice size was 8979 (IQR 5760, 11,986). (see Table 2) Based on the GP practice postcode we obtained Index of Multiple Deprivation (IMD), Deciles for each of the practices. These were then grouped into their respective CCGs. This shows that the CHES study drew its sample from across the total spectrum with some having practices from 1 (the most deprived 10% areas nationally) to 10 (the least deprived 10% areas nationally). The median overall being 5 (IQR, 2, 8).

Table 2. GP practices included in the CHES study grouped by clinical commissioning group (CCG).

Clinical Commissioning Groups (CCGs)		GP Practices (number, total population, median size)				*Index of Multiple Deprivation (IMD) Deciles	
		N	Tot	Median	IQR	Median	IQR
1	Coventry	11	95078	7927	(5803, 10595)	5.0	(2, 5)
2	South Warwickshire	11	98303	9292	(5391, 11654)	9.0	(8.5, 9)
3	North Warwickshire	7	65923	10256	(6852, 11580)	6.0	(4.5, 8)
4	Birmingham Cross City	15	126181	7295	(4408, 9194)	2.0	(2, 1)
5	East Staffs	11	90223	5743	(4209, 8964)	7.0	(5.5, 8.5)
6	Oxfordshire	14	170890	13294	(9693, 15249)	10.0	(9, 10)
7	North and West Reading	1	11637	11637	-	10.0	
8	Milton Keynes	3	30844	11178	(8489, 11178)	7.0	(6.5, 8.5)
9	Birmingham South Central	7	47976	5640	(5215, 7953)	3.0	(1.5, 4.5)
10	South Worcestershire	7	73954	11014	(7951, 12524)	7.0	(5.5, 7.5)
11	Nottingham City	8	69075	8890	(7311, 9103)	2.0	(1, 4.25)
12	Leicester City	3	24278	10230	(7024, 10230)	4.0	(2.5, 4)
13	East Leicester & Rutland	1	11119	11119	-	8.0	
14	Hereford	4	30295	8798	(7158, 9214)	5.5	(4.75, 6.25)
15	Bromley	4	33402	8402	(7727, 9025)	6.5	(5.25, 7.25)
16	Wandsworth	3	35446	11981	(10616, 13098)	6.0	(5.5, 8)
17	Camden	10	106936	10209	(5964, 14695)	4.0	(3, 6)
18	Southwark	10	98518	101158	(7114, 13073)	4.0	(3.25, 4)
19	Newham	6	54483	7759	(7139, 10365)	3.0	(3, 3)
20	Tower Hamlets	8	86463	12260	(8941, 13731)	2.0	(1, 2)
21	Lambeth	10	87143	7961	(6074, 11025)	3.5	(2.25, 4.75)
22	Hounslow	8	49311	5155	(4040, 8044)	5.0	(5, 6)
23	Redditch and Bromsgrove	2	26208	13104	(13028, 13180)	8.5	(8.25, 8.75)
		<b>164</b>	<b>1523686</b>	<b>8979</b>	<b>(5760, 11986)</b>	<b>5.0</b>	<b>(2, 8)</b>

\*IMD = Index of Multiple Deprivation . The deciles are calculated by ranking the 32,844 Lower-layer Super Output Area (LSOA) level in England from most deprived to least deprived and dividing them into 10 equal groups. LSOAs in decile 1 fall within the most deprived 10% of LSOAs nationally and LSOAs in decile 10 fall within the least deprived 10% of LSOAs nationally. [14]

Table 3. The CHESS GP practices grouped by CCG showing the percentage ethnic mix in each compared to national figures for England and Wales (Nationally 80.5% identify as White British, 4.4% other white ethnic group)

	Clinical Commissioning Groups (CCGs)	# GP Practices	% Mixed ethnicity			% Asian			% Black			% Other ethnic group			% All ethnic groups		
			Mean	SD	± nat average <sup>1</sup>	Mean	SD	± nat average <sup>1</sup>	Mean	SD	± nat average <sup>1</sup>	Mean	SD	± nat average <sup>1</sup>	Mean	SD	± nat average <sup>1</sup>
1	Coventry	11	2.46	(0.63)	0.26	14.25	(9.39)	6.75	5.59	(3.47)	2.29	1.76	(0.94)	0.76	23.58	(12.24)	9.58
2	South Warwickshire	11	1.27	(0.92)	-0.93	2.79	(2.68)	-4.71	0.34	(0.68)	-2.96	0.76	(0.92)	-0.24	4.96	(3.69)	-9.04
3	North Warwickshire	7	0.67	(0.63)	-1.53	4.40	(4.72)	-3.10	0.00	(0.00)	-3.30	1.30	(0.64)	0.30	6.37	(5.14)	-7.63
4	Birmingham Cross City	15	4.22	(1.30)	2.02	21.61	(19.79)	14.11	7.73	(2.26)	4.43	1.85	(4.12)	0.85	35.41	(21.14)	21.41
5	East Staffs	11	0.85	(0.89)	-1.35	4.25	(7.28)	-3.25	0.51	(0.92)	-2.79	1.11	(0.94)	0.11	6.71	(8.25)	-7.29
6	Oxfordshire	14	1.03	(0.57)	-1.17	1.95	(0.96)	-5.55	0.50	(0.70)	-2.80	0.41	(0.70)	-0.59	3.89	(1.40)	-10.11
7	North and West Reading	1	1.80		-0.40	2.10		-5.40	0.00		-3.30	0.00		-1.00	3.90		-10.10
8	Milton Keynes	3	2.53	(1.24)	0.33	5.10	(3.46)	-2.40	3.13	(2.72)	-0.17	0.00	(0.00)	-1.00	10.77	(7.35)	-3.23
9	Birmingham South Central	7	3.81	(0.88)	1.61	29.43	(24.54)	21.93	5.57	(2.88)	2.27	3.00	(4.55)	2.00	41.81	(30.05)	27.81
10	South Worcestershire	7	0.87	(0.68)	-1.33	2.17	(2.02)	-5.33	0.00	(0.00)	-3.30	0.45	(0.70)	-0.55	3.48	(2.09)	-10.52
11	Nottingham City	8	6.01	(1.66)	3.81	11.69	(8.22)	4.19	6.33	(2.46)	3.03	1.04	(1.20)	0.04	25.06	(11.39)	11.06
12	Leicester City	3	3.07	(0.76)	0.87	27.73	(37.73)	20.23	5.07	(2.40)	1.77	0.90	(1.56)	-0.10	36.77	(38.09)	22.77
13	East Leicester & Rutland	1	1.70		-0.50	8.40		0.90	0.00		-3.30	1.50		0.50	11.60		-2.40
14	Hereford	4	0.25	(0.50)	-1.95	0.28	(0.55)	-7.23	0.00	(0.00)	-3.30	1.03	(0.69)	0.02	1.55	(0.38)	-12.45
15	Bromley	4	4.20	(1.91)	2.00	5.63	(0.18)	-1.88	9.08	(8.02)	5.78	0.68	(0.68)	-0.33	19.58	(10.57)	5.58
16	Wandsworth	3	4.97	(0.87)	2.77	12.10	(6.55)	4.60	11.90	(7.63)	8.60	2.10	(0.56)	1.10	31.07	(13.24)	17.07
17	Camden	10	5.97	(0.45)	3.77	12.59	(2.68)	5.09	8.75	(3.52)	5.45	4.16	(1.26)	3.16	31.47	(6.56)	17.47
18	Southwark	10	6.01	(0.42)	3.81	13.52	(2.44)	6.02	23.67	(7.95)	20.37	3.65	(0.45)	2.65	46.85	(6.52)	32.85
19	Newham	6	4.68	(0.78)	2.48	40.50	(12.01)	33.00	20.90	(3.33)	17.60	3.47	(0.33)	2.47	69.00	(6.75)	55.00
20	Tower Hamlets	8	3.58	(0.40)	1.38	49.64	(6.33)	42.14	7.10	(2.34)	3.80	2.19	(0.32)	1.19	62.50	(6.45)	48.50
21	Lambeth	10	7.60	(0.70)	5.40	7.95	(2.99)	0.45	28.10	(8.17)	24.80	2.61	(0.65)	1.61	46.26	(8.62)	32.26
22	Hounslow	8	4.00	(0.77)	1.80	33.43	(21.45)	25.93	6.56	(1.13)	3.26	3.69	(1.60)	2.69	47.68	(22.46)	33.68
23	Redditch and Bromsgrove	2	1.30	(0.14)	-0.90	2.10	(0.00)	-5.40	0.00	(0.00)	-3.30	0.00	(0.00)	-1.00	3.40	(0.14)	-10.60
		<b>164</b>	<b>3.39</b>	<b>(2.32)</b>	<b>1.19</b>	<b>14.42</b>	<b>(17.07)</b>	<b>6.92</b>	<b>7.57</b>	<b>(9.06)</b>	<b>4.27</b>	<b>1.88</b>	<b>(2.10)</b>	<b>0.88</b>	<b>27.09</b>	<b>(23.38)</b>	<b>13.09</b>

<sup>1</sup> Data for the percentages of ethnic groups within England and Wales were taken from Census data (2011) These were: 7.5% - Asian, 3.3% Black, 2.2% Mixed Ethnicity & 1% Other. These national averages were subtracted from the averages found in each CCG to indication differences.

Table 3, shows the representative ethnic variation across the CHES study GP practices and their respective CCGs. Reflecting the differences in areas that were included, these range from areas with a very low proportion of people from minoritised ethnic groups (i.e. not from White British or “other white” ethnic group) (mean 1.55% SD 0.38) to areas with a high proportion (69% SD 6.75). Overall the GP practices included had a greater than average population from minoritised ethnic groups (27.09% SD23.38) just over 13% greater than the averages for England and Wales.

## Recruitment

Table 4 below groups the GP practices involved in CHES by the Index of Multiple Deprivation (IMD) decile score for the postcode of the practice location. The practices are found in all ten of the IMD deciles from 1 (the 10% most deprived areas nationally) to 10 (the 10% least deprived areas nationally). Searches carried out at each practice identified a total of 31,020 patients (2.04%) of the practice populations, who met the screening criteria, who were then approached as potential participants for the study. Of those contacted 2178 (7.02%) were interested with 1034 (47.47%) of these meeting the eligibility criteria. A total of 706 (68.28%) of eligible and interested were randomised into the study.

Table 4. CHES recruiting GP practices grouped by index of multiple deprivation deciles

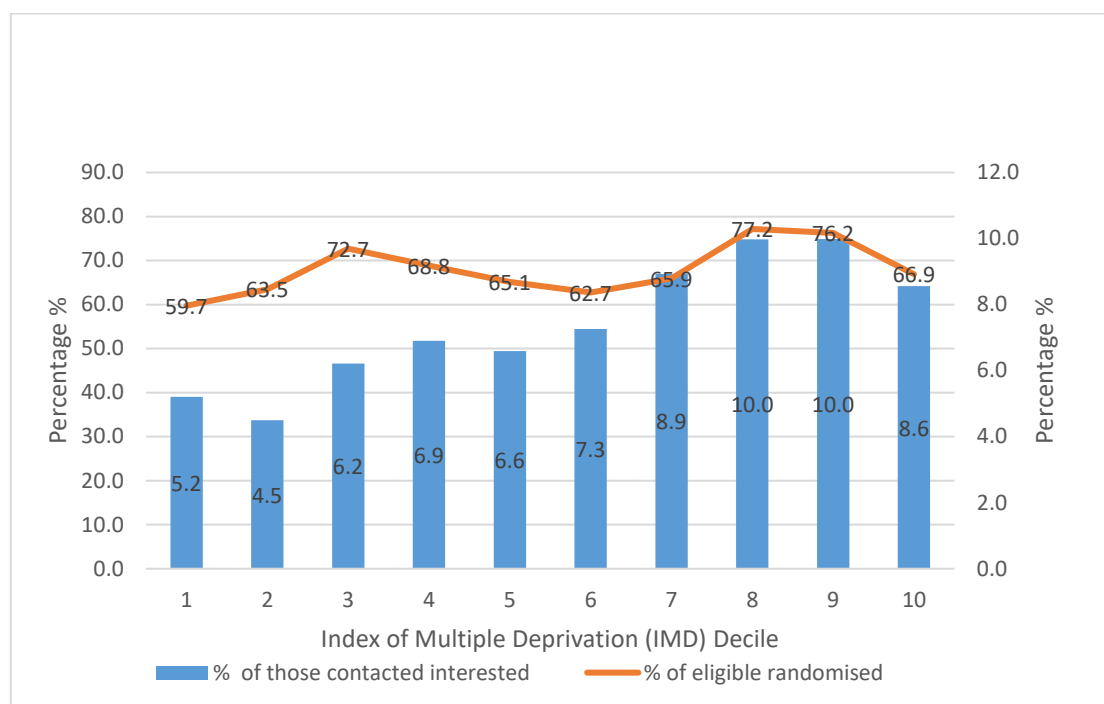
*IMD	Number of practices	Patient Population of practices	Size of practices by patient population		identified at practices and contacted		interested		Interested & eligible		Eligible & consented		Eligible & randomised	
Dec	N	Tot N	Median	IQR	N	%	N	%	N	%	N	%	N	%
1	16	125898	7199	(5103, 9240)	2919	2.32	152	5.21	77	50.66	51	66.23	46	59.74
2	26	217409	8732	(6343, 10841)	5425	2.50	244	4.50	115	47.13	78	67.83	73	63.48
3	15	160651	7852	(7232, 12327)	2816	1.75	175	6.21	77	44.00	62	80.52	56	72.73
4	18	140742	6629	(5377, 10045)	2913	2.07	201	6.90	93	46.27	67	72.04	64	68.82
5	21	194130	9250	(5582, 11300)	3958	2.04	261	6.59	129	49.43	88	68.22	84	65.12
6	16	154602	10048	(5498, 12515)	3169	2.05	230	7.26	102	44.35	70	68.63	64	62.75
7	9	58016	4820	(3317, 9000)	1344	2.32	120	8.93	44	36.67	35	79.55	29	65.91
8	13	123674	9474	(6821, 12215)	2395	1.94	239	9.98	127	53.14	99	77.95	98	77.17
9	14	172112	12016	(7983, 16465)	2483	1.44	248	9.99	122	49.19	99	81.15	93	76.23
10	16	176452	11809	(8225, 14084)	3598	2.04	308	8.56	148	48.05	106	71.62	99	66.89
All	164	1523686	8979	(5760, 11986)	31020	2.04	2178	7.02	1034	47.47	755	73.02	706 <sup>a</sup>	68.28

\*IMD = Index of Multiple Deprivation . The deciles are calculated by ranking the 32,844 Lower-layer Super Output Area (LSOA) level in England from most deprived to least deprived and dividing them into 10 equal groups. LSOAs in decile 1 fall within the most deprived 10% of LSOAs nationally and LSOAs in decile 10 fall within the least deprived 10% of LSOAs nationally.

<sup>a</sup> 30 participants were self-referrals and not attached to a particular practice so are not included here.

Figure 2 compares the percentages of patients who were contacted and responded with interest with those from this group who were eligible for the trial and consented to be randomised, grouped by the IMD Deciles that they came from. There is a slight trend for more interest in the study from areas with lower levels of deprivation (8.9%, 10%, 10% & 8.6%) compared to (5.2%, 4.5%, 6.2% & 6.9%) in areas with high levels of deprivation. However, conversion from those who do express an interest and who are eligible to consenting and randomisation remained at similar levels throughout.

Figure 2. Chart showing percentages of potential participants who were interested and from these those who were eligible and randomised



One important issue in terms of recruitment is that the study team only recruited 9 participants who were believed to have tension type headache. The study is predominantly populated with participants who were believed to have migraine (See study consort chart).

### Expression of Interest forms

We examined the expression of interest forms for the first 85 eligible people who were approached but declined participation and who provided feedback/reasons for not wanting to participate. The feedback form gave them eight options (see Table 5) and they could tick more than one if they wished. There was also an 'other' for which they could provide a free text response.

Most reported their headache was not currently that bad. Secondly, time to be able to participate seemed to be an issue and some felt they did not wish to participate in the group sessions.

Table 5. Reasons not interested in participating in the CHES trial

Reasons		Single tick	Multiple ticks	Total
1	I don't have headaches	8	5	13
2	My headaches are not very bad at the moment	21	14	35
3	My headaches are too bad at the moment	1	3	4
4	I do not want to participate in a group programme	1	17	18
5	Attending the headache self-management programme will take up too much of my time	4	18	22
6	I do not want to fill in questionnaires	0	8	8
7	I do not want to participate in a telephone interview with a nurse	0	7	7
8	I do not want my treatment to be chosen at random	0	9	9
	Other	13	15	28

'Other' responses given in free text fell into 3 main categories;

1. Comments which resonated with: 2. My headaches are not very bad at the moment
  - 'I don't fit your criteria'
  - Controlled by medication/job change/circumstances
  - 'Anymore'
2. Comments which resonated with: 5. Attending the headache self-management programme will take up too much of my time
  - Due to work commitments
  - Family commitments including being a carer
  - Other health conditions/treatment taking priority
3. Those who ticked 4, 5 or 6 boxes N=7 gave no comments

## Dose Delivered

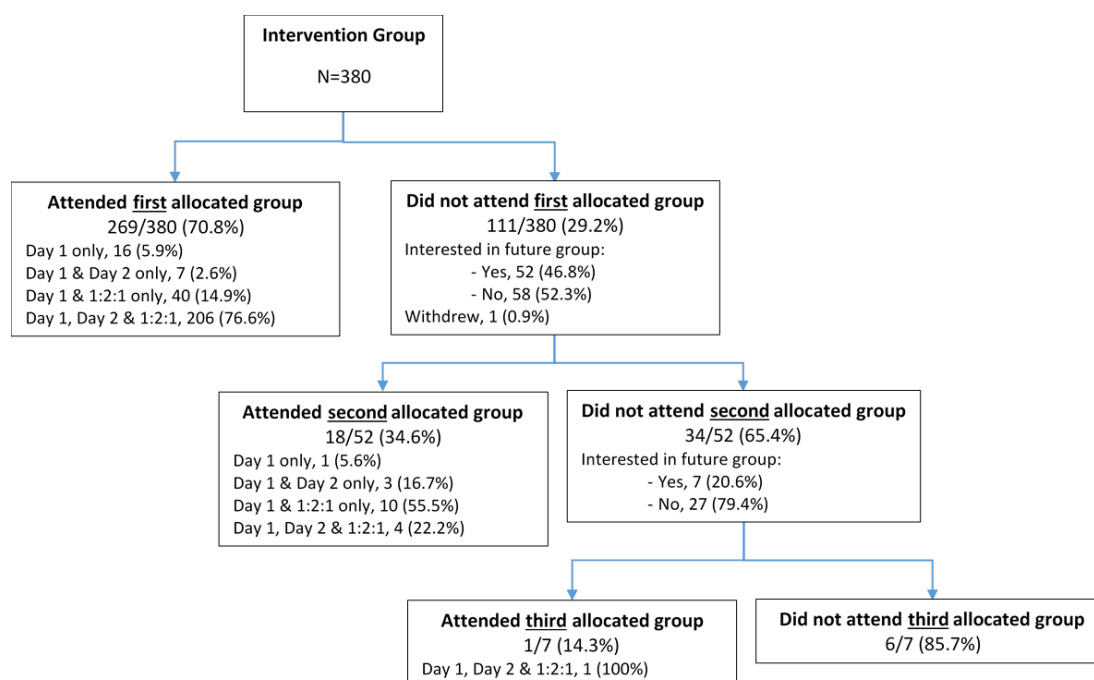
The protocol specified that 30 group sessions would be delivered, however additional sessions were added to make it possible for potential participants to attend. In the end a total of 43 groups were planned with only one of these cancelled. Of the 42 groups delivered 30 of these centred on the base at the University of Warwick and 12 were based out of Queen Mary, University London. Venues for groups included rooms within GP practices, health centres, community centres and walk in centres all located within close proximity to one or more recruiting GP practices. All venues were accessible and could accommodate participants with disabilities. Table 6 below outlines the geographical areas where groups were delivered.

Table 6. Areas in the UK where CHESS groups were delivered.

Locations and number of groups		Locations and number of groups	
Bedworth - Midlands	1	Nottingham - Midlands	2
Birmingham - Midlands	3	Nuneaton - Midlands	1
Bromley - South London	1	Solihull - Midlands	1
Camden - North London	2	Southwark - South London	3
Coventry - Midlands	3	Stratford upon Avon - Midlands	1
Hereford - Midlands	1	Tower Hamlets - North London	2
Hounslow - London	1	Tutbury - Midlands	2
Kenilworth - Midlands	1	Abingdon – Thames Valley	2
Lambeth - South London	1	Wandsworth - South London	1
Leicester - Midlands	1	Wantage – Thames Valley	1
Lichfield - Midlands	2	Warwick - Midlands	3
Milton Keynes – Thames Valley	1	Witney – Thames Valley	1
Newham - North London	1	Worcester - Midlands	3

If participants could not attend the first group they were offered they were offered an alternative (up to a maximum of three offers). Median group sizes at allocation were 10 (IQR 8, 13) across the 42 groups (note this was allocation to groups not attendance). See Figure 3 below

Figure 3. Intervention participant allocation flow diagram



## Dose Received

A total of 380 participants were invited to attend the two-day group sessions and the 1-2-1 discussions with a nurse.

### Two-day intervention courses

From this 380 there were 288 (76%) that attended at least part of the two-day course. However this does mean that 92 (24%) were not exposed to the CHES intervention at all.

Of the 288 who did attend the group sessions 227 (79%) attended both days with 61 (21%) only attending day one.

### One-to-nurse appointments

Participants who took part in the group sessions were given the opportunity for a one-to-one discussion/consultation with the CHES nurse to discuss progress and medications after the first day of attendance. Of the 288 who took part in groups 261 (91%) had a one-to-one interaction with the nurse.

### Adherence

A priori we defined a minimum dose of the intervention as attendance at day one and engaging with the nurse in a one-to-one session. Therefore of the 380 participants in the intervention arm, 261 (69%) achieved this pre-determined minimum dose. Only 217 (57%) achieved full adherence (attended both days and had the one-to-one session).

### Reasons given for being unable to attend

Throughout the study we collected any reasons participants gave to the trial team for being unable to attend any components of the intervention and categorised the responses for the Midland and London areas. The main reasons were regarding work or other family/friend commitments or being unwell or having migraines. Full data is provided in Appendix 1.



## Experiences of participating in the trial

### Intervention delivery staff focus groups

Four focus groups were held. Each focus group was divided into two parts: in the first part all facilitators and nurses participated, the second part was limited to the nurses to enable them to comment on nurse specific aspects of the intervention, such as the nurse consultation sessions and the nurse specific training they received.

- Friday 10<sup>th</sup> May 2019 Midlands region held at Warwick CTU.
- Attendees:- Nurses: 8 Allied health professionals: 2
- Thursday 16<sup>th</sup> May 2019 London region held at QMUL
- Attendees:- Nurses: 4 Allied health professionals: 2

Findings from the groups were summarised and combined.

### Box 1. Topic guide for discussions with staff.

#### *All facilitators:*

1. Was your training sufficient to deliver the CHES group intervention? Are any changes needed?
2. From your experiences what would be the ideal venue?
3. How did you find the support and communication with the members of the CHES team at the Clinical Trials Unit/Queen Mary's? Admin/quality assurance and trainers
4. Positive aspects and challenges for each session of Day 1 and 2

#### *Nurse Facilitators only:*

1. Was your training sufficient to deliver the nurse components of the CHES intervention?
2. Positive aspects and challenges of the 121 sessions:
  - Classification
  - Medication
  - Goal setting
  - Telephone calls

Findings from the groups were summarised and combined. Results are presented below grouped under the questions asked (see also Box 1). Along with each response is a series of suggestions or issues.

### All facilitators

#### *1. Was your training sufficient to deliver the CHES group intervention? Are any changes needed?*

- Generally they felt well prepared to deliver the groups. The training was thorough and very organised with a comprehensive manual. Newsletter hints and tips were useful.

Here the staff provided useful feedback providing suggestions and issues related to their involvement in the delivery of the intervention.

#### *Issues/ suggestions:*

- Most put in a lot of unpaid preparation time
- There was often a delay between training and intervention delivery. Some participants had refresher training, others would have liked this.
- Participants would have liked more input around practically taking a group themselves, or simulations, or having a CD/Film of a group session(s) in action.
- There was a desire for more training on taking mindfulness and relaxation

2. *From your experiences what would be the ideal venue?*

- Ideally venues need to have: good parking, transport access especially the London area, easy to adjust lighting, heating and enough space (not too cramped). Venues need to be safe i.e. with other people around, (felt safer in healthcare buildings rather than a community space with no staff). Comfortable chairs, visible green space and a calming environment would be good. It was suggested by some that venues should be more carefully selected so that they could provide an appropriate environment for this group of people.

3. *How did you find the support and communication with the members of the CHESS team at the Clinical Trials Unit/Queen Mary's? Admin/quality assurance and trainers?*

- WM group: Generally good with good backup support.
- London: Good support from local team whilst delivering. Set up problems in London getting occupational health checks. Payments delayed from UOW which seemed overly bureaucratic. Lack of communication and information about getting the paperwork done. (some almost dropped out due to this). Hold ups with research passports.

Both regions:

- Always someone to answer queries and got back to them, excellent responsive team. Newsletter helpful, felt part of the team.
- QA on first session good to help with setting up which was stressful in a new environment. QA generally well received as supportive and constructive and gave immediate feedback.
- Always the possibility of IT failure on the day (but most found a way to deliver with the materials given.)

4. *Positive aspects and challenges for each session of Day 1 and 2 (see Table 7)*

- Most sessions were easy to deliver and were well received. Both regions gave some insight into individual sessions some of which may need some minor revision if this intervention is implemented elsewhere for people with chronic headaches

Table 7. Feedback on specific CHESS sessions from those delivering the intervention

Sessions	Facilitator feedback
Session 3: Headache information	<ul style="list-style-type: none"> <li>• Long session. Triggers may benefit from being a separate session.</li> <li>• Very little on Tension type headache people may feel it's just for migraines.</li> <li>• Challenge to explain biological mechanisms</li> <li>• MOH introduction useful but occasionally evoked emotional responses (WM only)</li> <li>• Some resistance to classification.</li> </ul>
Session 4: Acceptance	<ul style="list-style-type: none"> <li>• Facilitators and some participants didn't like scenario.</li> <li>• Facilitators felt this was an important session but needs to be delivered differently.</li> </ul>
Session 5: Impact of thoughts mood and emotions on headaches	<ul style="list-style-type: none"> <li>• Rethink needed on delivery and the link between mood and headaches. Difficult for participants to offer 'less bad' scenarios.</li> </ul>
Session 6: Headache cycle & Breaking the cycle	<ul style="list-style-type: none"> <li>• Well-liked by facilitators but the message is not quite right. The word 'breaking' seems unhelpful.</li> <li>• Some participants felt medication was the 1st line of response but it did open up the idea which was picked up by some in the 121 sessions.</li> <li>• Difficult to introduce depressive thinking (WM)</li> </ul>

	<ul style="list-style-type: none"> <li>If no 'buy in' by participants in previous session 5 then this session doesn't work as well (Lon)</li> </ul>
Session 7: Unhelpful thinking patterns: recognising and finding alternatives.	<ul style="list-style-type: none"> <li>Generally enjoyable session, promoting disclosure and sharing. Participants were tired by this time, busy slides with too many examples. Examples of facilitators doing this session differently e.g. whole group, smaller groups, using tables, walking to cards on the floor, looking at cards on floor, gave handouts instead of slides. (group numbers may dictate this.)</li> <li>DVDs Some watched with family which was helpful some didn't like the actress or GP.</li> <li>CDs Need to consider different formats not everyone can play DVDs</li> </ul>
Session 10: Identifying barriers to change and exploring problem solving and goal setting	<ul style="list-style-type: none"> <li>Useful session. Some using goals but not SMART, some resistance to the idea. (LON)</li> <li>Pacing can be tricky (LON)</li> </ul>
Session 11: Lifestyle factors and impact on headaches	<ul style="list-style-type: none"> <li>Important to have in even if some 'know it all'. Promotes sharing. Flexible delivery</li> </ul>
Session 12: Managing stress and anxiety	<ul style="list-style-type: none"> <li>Care needed to get the tone right, not to blame or patronise. Clarification needed on emotional/behavioural and stress/anxiety</li> </ul>
Session: 13: Managing sleep better	<ul style="list-style-type: none"> <li>Important and interesting. Some facilitators had read around the subject – would have liked more information 'Try and stay calm/relaxed' vague and unhelpful.</li> </ul>
Session 14 : Mindfulness and relaxation for headaches	<ul style="list-style-type: none"> <li>Facilitators would like more knowledge to feel confident about delivering.</li> </ul>
Session 15 : Medication management	<ul style="list-style-type: none"> <li>This session seemed to have a muddled message re acute and preventative.</li> <li>Asking participants about their medication not useful here. Perhaps this should be an information giving session only and discussions should be at the 121 session. Difficult to stop participants giving each other medical advice about dosages or other medication they may be on e.g. opioids.</li> </ul>
Session 16: Relationships and communication with family, carers and friends.	<ul style="list-style-type: none"> <li>Some participants didn't want to engage. (LON)</li> </ul>
Session 17 : Communicating better with Health Professionals	<ul style="list-style-type: none"> <li>Care needed not to turn it into a moaning session especially if they felt it was the GPs fault.</li> </ul>
Session 18: Managing setbacks	<ul style="list-style-type: none"> <li>Too soon to know about managing any setbacks. Difficult session to deliver could be patronising (LON). Perhaps better covered in 121.</li> </ul>
	<ul style="list-style-type: none"> <li></li> </ul>
Handouts	<ul style="list-style-type: none"> <li>Alternative formats might have been useful. e.g. web page.</li> </ul>
Note: Session 1 & 2 Welcome and introduction were not mentioned	

## Nurse facilitators

### *Nurse Specific Training:*

- Training and training team excellent.
- Would have liked more role play (different scenarios) to use diaries and algorithm together – some given in training which was really valuable. 'Not as easy in real life!'
- Backup support really valued as they felt a responsibility to get a correct classification - needed reassurance which they got from the team.
- Perhaps a backup system for debriefing as participants 'offloaded' their concerns and worries a lot.
- Manual very helpful.
- Lag between training and delivery unhelpful.

### *121 sessions:*

#### *Generally*

- Unpaid prep work needs to be factored in.
- Some sessions were done as telephone calls which decreased travel but nurse then had no diary to refer to-so completed the session by increased questioning.
- Participants often divulged a great deal of personal information so some debriefing would have been helpful.
- Some instances of lone worker issues e.g. doing 121 sessions in a building alone.

#### *Classification:*

- A few participants were unhappy about their classification with some feeling it did not describe their headache with some not believing the classification. Some facilitators felt it necessary to changed their wording when explaining the classification to 'for the purposes of the study' so that participants were more accepting.

#### *Medication:*

- Happy to signpost to GP about possible medication changes.
- Some resistance to change from some participants.
- MOH good discussions, always put back to patients rather than anyone 'taking their medications away'.
- MOH 'You could see the penny drop'. Most cut down gradually many with good results.

#### *Goal setting:*

- Some brought SMART goals, some didn't. Setting goals is a facilitator skill (maybe more is needed in training). Perhaps need a new way of introducing when not good at writing down e.g. Apps, role play.

#### *Telephone calls*

- 'Participant led' by what they needed. Mainly to keep people on track with lifestyle changes and goals.
- Practical difficulties with contacting participants some asked for out of hours calls. Payment an issue for random timings and missed calls.
- Facilitators felt some had decreased their medications but some started taking new medication e.g. triptans.

## Participant Interviews:

### Participant characteristics

Table 8. Baseline characteristics of participants interviewed compared against the overall trial population.

Characteristics	Interviewees (N=31)	Overall (N=736)
Age (years)		
<b>Mean (SD)</b>	46.9 (16.0)	47.6 (15.0)
Gender		
<b>Male</b>	6 (19.4%)	126 (17.1%)
<b>Female</b>	25 (80.6%)	608 (82.6%)
<b>Missing</b>	0	2 (0.3%)
Locality		
<b>Greater London</b>	6 (19.4%)	221 (30.0%)
<b>Midlands</b>	25 (80.6%)	515 (70.0%)
Ethnicity		
<b>White</b>	26 (83.9%)	595 (80.8%)
<b>Black or Black British</b>	3 (9.7%)	42 (5.7%)
<b>Asian or Asian British</b>	1 (3.2%)	60 (8.2%)
<b>Mixed</b>	0	21 (2.8%)
<b>Other</b>	0	8 (1.1%)
<b>Missing</b>	1 (3.2%)	10 (1.4%)
Employment status		
<b>Employed</b>	16 (51.7%)	418 (56.8%)
<b>Unemployed</b>	1 (3.2%)	23 (3.1%)
<b>At school or full time education</b>	1 (3.2%)	23 (3.1%)
<b>Unable to work due to long term sickness</b>	4 (12.9%)	69 (9.4%)
<b>Looking after home/family</b>	1 (3.2%)	44 (6.0%)
<b>Retired from paid work</b>	6 (19.4%)	120 (16.3%)
<b>Other</b>	1 (3.2%)	27 (3.7%)
<b>Missing</b>	1 (3.2%)	12 (1.6%)
Age left full time education		
<b>Did not receive formal education</b>	0	4 (0.5%)
<b>Age 12 or less</b>	1 (3.2%)	5 (0.7%)
<b>Age 13 to 16</b>	9 (29.0%)	178 (24.2%)
<b>Age 17 to 19</b>	12 (38.8%)	203 (27.6%)
<b>Age 20 or over</b>	7 (22.6%)	307 (41.7%)
<b>Still in full time education</b>	1 (3.2%)	27 (3.7%)
<b>Missing</b>	1 (3.2%)	12 (1.6%)
Headache classification		
<b>Definite chronic migraine</b>	13 (41.9%)	396 (53.8%)
<b>Probable chronic migraine</b>	17 (54.9%)	331 (45.0%)
<b>Tension type headache</b>	1 (3.2%)	9 (1.2%)
Medication overuse		
<b>No</b>	17 (54.8%)	326 (44.3%)
<b>Yes</b>	14 (45.2%)	410 (55.7%)

## CHES participant interviews

We purposively sampled 26 participants from the main trial to ensure a range of characteristics and invited them for interview. Table 8 shows that our interviewee sample was generally representative of the whole trial sample although we note that those interviewed generally came from the group who reported lower levels education attainment. The interview study was challenging firstly due to the short time window to book a face to face interview between consent and randomisation and contacting people especially at later time points by telephone was difficult to book interview appointments. It was also difficult to contact participants by phone to collect follow-up core questionnaire data. London participants on the whole were more difficult to contact than those in the West Midlands and are less well represented in the interview study.

Table 9 gives an overview of the interviewee sample and the timings of the interviews. Five were unable to attend appointments and the interviews could not be rearranged prior to randomisation. 21 were seen after completing their consent and baseline paperwork before being randomised. Twenty three further people were invited from both the Midlands and London area for interview at 4months post randomisation but only 10 people could be contacted or agreed to interview. All interviewees were sent a patient information leaflet and completed an informed consent before being interviewed. Interviews were audio recorded on an encrypted digital recorder and lasted around an hour. Recordings were transcribed verbatim and checked for accuracy by the researcher before using an NVivo software programme to organise the data.

Table 9. Interview sample and timelines

	Baseline Face to face (Taken prior to randomisation) n=21 (4 London)	4ms ( majority face to face) n= 28 (6 London)	12ms (Telephone) n=23 ( 4 London)
<b>Midlands</b>	8 Control 3 Intention to treat* 6 Intervention	7 Control (1 withdrew from trial/ health reasons) 1 Intention to treat (2 declined) 6 Intervention	6 Control (1 n/a due to social circumstances) 0 Intention to treat (unable to contact) 6 Intervention
<b>London</b>	2 Control 1 Intention to Treat 1 Intervention	2 Control 1 Intention to Treat 1 Intervention	1 Control (1 not appropriate in hospital) 1 Intention to treat 0 Intervention (1 Unable to contact)
<b>Totals</b>	<b>10 Control</b> <b>4 Intention to treat</b> <b>7 intervention</b>	<b>9 Control</b> <b>2 Intention to treat</b> <b>7 Intervention</b>	<b>7 Control</b> ) <b>1 Intention to treat</b> ) <b>14 longitudinal vignettes</b> <b>6 Intervention</b> ) <b>(2 London)</b>
		4ms (additional intervention only)	12ms (additional intervention only)
	Midlands	8	7 (1 n/a marked memory problems)
	London	2	2
	<b>Sub Total</b>	<b>10</b>	<b>9</b>
	<b>Total to comment on the intervention</b>	<b>17 ( 2 London)</b>	<b>15 Intervention at 2 time points – ( 2 London)</b>
*Intention to treat participants are those who were randomised to the intervention but did not take part in any intervention activities			

Below we present the results from the interviews, firstly we present the results from those participants who were randomised to the control intervention. Then we present results from those who were randomised to receive the CHES intervention who were interviewed at four and twelve months post-randomisation. These results are summarised, more detailed information including additional quotations can be found in Appendix 2 & 3.

## 1) Usual care and Relaxation Arm interview analysis

Of the baseline interviewees (21) one control participant withdrew from the trial for unrelated health reasons, and 4 who were allocated to the intervention arm didn't attend the groups and were analysed as Intention to treat. This is data is from nine participants plus two intention to treat participants (the other two of these participants declined a 2<sup>nd</sup> interview - one due to health reasons and one said they were too busy). Below is a summary of the results there are additional quotations and information in Appendix 2 & 3.

### Relaxation CD

Some didn't use the relaxation CD either because; they didn't have a CD player (2), they didn't think it would help them personally (2)

*...but I haven't actually listened to it because I don't have a DVD player...14*

Two preferred a phone App for its portability, one had used other relaxation phone Apps and one of these managed to get the CHESS application to play on a mobile (this was not a usual route of administration in the study).

*... I don't generally play CD's... mmm... if I want to listen to music or whatever I'll probably do it on my iPhone or television...07*

*We tried to do it but I couldn't... I couldn't download it!.....but no we couldn't do it so the only way we could actually do it was to get it on my phone.....sorry... it's easier for me to do it actually because it means I can... wherever I go...20*

Contextual issues were raised by 4 participants mainly to do with not having the time to devote to relaxation in their lives generally or when other life events had taken priority e.g. a relative's illness or looking after a toddler.

*but it's finding two days a week... 17 minutes when you've got other things going on...20*

One tried the CD but found it made their headaches worse from using it during a headache because of the noise and abandoned it when it didn't help and they couldn't find the time to use it regularly.

*...listening to it made me feel worse because it was a noise that was irritating more than anything...  
...whereas when I have headaches the silence is like a godsend! 04*

Two used the CD, one twice a week and the other for a few months and found the relaxation helpful.

*... it can often send me to sleep which is... mmm... you are so relaxed and you are so tired at the end of the day... I probably listen to it a couple of times a week...11*

Three spoke of their expectations of using the CD; 2 felt it was not going to help them at the outset but one was enthusiastic about the possibility of using the CD to help their headaches.

*... I wanted to do it because I thought it was going to help my headache...20*

One didn't remember receiving a CD or letter (these were resent by the trial team after consultation with the PI)

### Information Letter

Two didn't recall reading any information which came with the CD and one didn't mention it at interview. Those who recalled it felt it was useful either as a reminder of what they already knew making them think about how it may have been personally relevant.

*it was really interesting you know.....Some bits I knew and some bits I didn't you know it's like I know they were caused by lack of sleep that's one thing that applies to me...12*

Some felt they had gained new knowledge such as the range of medications which were available or the effect of triggers or sleep.

*... some of the Beta-blockers and things I didn't know about but yeah..... everything that has been sent out has been really useful...20*

Having this information also served to normalise one participant's headaches and validated the headache experiences for two others.

*... I found to be honest I found being part of all of this really great I mean I felt like... I mean everything I've read... everything I've received I thought it was amazing... mmm... you know I'm so glad I've done it because it's made me a lot more aware of my migraines... ... and actually being able to say, 'Oh I've been part of a study.' It's like, 'Oh god you know that is something more serious than we thought.' It was, so that has made me feel better... it's given me more of a confidence to say, 'OK this is horrible. I deal with it'...10*

For those who spoke about medication overuse headaches some felt they already knew about this phenomenon although it wasn't clear how much they understood on giving their explanations of it.

### Suggestions for changes

Four people said they would recommend this approach to others and one wouldn't recommend it to everyone but felt it would be useful for people who were newly diagnosed. Three wanted the CD in a more accessible form such as MP3 to play on a phone, one felt the CD was too long.

Two would have liked to be able to talk to others about their headache.

One wanted more individual tailoring of the advice and a choice of background music and different voices on the relaxation CD. No suggestions were made as to how we could improve the information which was well received and contained new information for some and was a refresher for others as a source of up to date information about headaches and its treatment.

### 2) About the group intervention 4ms post randomisation.

Results summarised below additional quotations and information can be found in appendix 4.

#### Would you recommend this course to others?

Responses from 16/(17) intervention participants interviewed at 4ms showed that all participants said that they would recommend the intervention they received to others for various reasons.

There were seven themes; useful information, meeting/discussing with others, self-management, having the right attitude, a different perspective, overall a good experience and 'not for them.' Some participant's responses crossed multiple themes.

- Nine people said that it had given them useful information either about headaches or what things they could try.
- Six valued meeting and discussing their headaches with other people in a similar situation either to talk or to listen to others about their experiences or to swap ideas. 'In the same boat' 'not alone' Shared experience/ lessened isolation.



- Four valued a self-management approach with a range of different things to try.
- Two felt that you needed the right attitude to get the most out of the group.
- Two spoke about learning about themselves giving them a different perspective on their headaches.
- Two just said that it had been good without specifying why.
- Three felt it hadn't necessarily been useful for them but might be useful for others, one of these felt it may have been more useful for people who were newly diagnosed rather than those who were more self-aware or knowledgeable about headaches.

### Venue

Ten participants commented on the group venue. Four felt their venue was ok, the others cited a variety of specific issues; Poor ventilation/ temperature control (3), poor parking (2), artificial lights (2), cramped space (2), external noise (1) and poor signage for group (1).

### Facilitation

Fourteen people commented on how the facilitators delivered the course.

The majority felt the groups were well run and were positive about the course delivery.

*... the two people that were running it were great and they were very accommodating for us because if we went off track they were happy to let us just explore what we were... we were talking about...31*

Four commented on the relaxed environment of the groups.

*... the ladies who lead the course were very good... I think we all felt very relaxed and easy... you know easy to chat...27*

On the whole people valued the opportunity to talk in a group and discuss headaches. However some people didn't get on with specific aspects relating to the facilitators.

Three people wanted more expert input into the group one commenting that the facilitators were not experts in headache. Two felt the pace was fine but would have wanted it quicker for themselves. One felt the pace was a bit slow.

Two people didn't gel with one of their facilitators.

Two felt that one of their Facilitators had delivered some sessions poorly where some sessions weren't explained adequately and one where the facilitator just seemed to read from the slides or manual.

*... the way it was executed by the person who was doing the facilitation was a bit muddled up so we didn't fully understand what we were supposed to be doing... mmm... and then she did spend a whole couple of minutes literally reading... through the slides! 25*

The group intervention was well received and when people talked generally about the whole intervention the overwhelmingly prevalent theme in the data was the value they placed on the group experience enabling them to meet with others to share, explore and discuss their headaches.

### The Group Experience

Seventeen participants commented about being in a group which almost all found a helpful and positive experience. Five themes were elicited from the data: 1) Discussion and sharing 2) shared experience of headache 3) comparing 4) less isolated and 5) potential alienation. Some talked about multiple themes. Fourteen said they valued discussion and sharing within the group. Contributing to the discussions and listening to others gave them new ideas and coping strategies.

*... like in general I think it was super helpful to have a group of people who basically suffer about the same things so the levels of kind of sharing and empathy and just understanding and listening were a special thing...25*

Some also felt that other people's experiences helped them to consider things from a different perspective.

Eight liked the idea that they were with people in the same boat which gave a feeling of a shared experience of living with headaches and a common purpose for attending.

*Just being able to talk to other people that... that suffered as well... that were suffering as well cos then shared experiences... shared tips... how to control them without the pain... yeah because we all didn't want... we all wanted to come off painkillers we were all fed-up of taking painkillers so any other ideas of how to control was helpful...28*

Eight spoke about comparing themselves to others within the group especially those who felt that their headaches weren't as bad. This made them feel lucky and made them feel more positive about their headaches.

*... I mean I know there are other people out there that have migraine I suppose I didn't realise there were so many people who took the same medication as me and that it's so widely used and it's reassuring to know that the people taking the medication and how they take it and it was very similar to me...27*

Seven said that attending the group had lessened feelings of isolation, of 'them being the only one.' Finding out there were others in a similar situation was helpful.

*... the group discussion was actually very good and a lot of people enjoyed that and they came away with a lot more positive thinking because knowing that they are not the only ones out there so you know you go in there and think I am the only one that suffers like this... 24*

Although almost everyone had got something out of the group in terms of meeting with a group of people with similar experiences, there were elements of the group which had the potential to segregate participants. This was mostly due to the personal relevance of the group. Three felt that the group was more for those at work.

*...we did talk about this on the course because I'm retired it affects me differently to the way that course had been planned... err... and presented was more for people who work and what to do for work and understandably you know... if I have a very bad migraine I can stop if you work you can't...19*

One felt that the group was aimed at those who hadn't had headaches for long (who may lack knowledge about headaches). One felt a lot didn't apply to them as they had tension type headache and there was more information about migraines, this person also felt a bit daunted by the group and didn't understand some of the exercises.

*...but all the other people seemed to have migraine headaches and it seemed... I thought it seemed to focus more on managing migraine headaches than tension headaches you know there was far more information and they were all discussing things like what medication they were on and different things like that and I thought well that doesn't apply to me so I thought a lot of the things like on the paper work that they gave us afterwards you know it says like other resources there were like three migraine things but there was nothing much else for tension headaches...08*

There were some comments about potential gender issues. One male participant said the course was biased towards females another woman felt that women may be uncomfortable talking about hormonal triggers which may make men feel 'out of it.'

*... it was quite a diverse group of people I think... mmm... and... err... it was very biased towards females there was just two men...09*

Only one felt that they got nothing from the group.

Another (24) felt they had valued the discussion but overall it wasn't helpful as they felt the group facilitators thought that participants didn't know anything when a lot knew a great deal.

### Intervention sessions

Table 10 presents an overview of the responses from interviewees when asked about the specific sessions through the intervention. The results reveal that overall the sessions were acceptable there were some sessions that were liked more than others and some sessions that were felt to be irrelevant.

Table 10. Interviewee responses to questions about specific sessions within the two day programme.

Day1. Living, understanding and dealing with chronic headaches Findings	
<b>Sessions 1, Welcome &amp; 2, Introduction</b>	No specific comments on these
<b>Session 3.</b> Headache information and mechanisms	<p>Participants on the whole seemed well informed about headaches. Fourteen commented on this session (some giving more than one response) and three stated it was generally useful. Others (7) felt they had gained new information about characteristics and classification of the different kinds of headache including identifying with features of migraine such as prodrome (2), medication overuse (1) and triggers (1). Only 2 participants felt they knew all the information already. The one participant who had tension type headache stated that they would like to have known their headache prior to the group to make the information more personally relevant. (Participants were given their classification at the 121 sessions.)</p> <p>Fourteen spoke about medication overuse headaches.</p> <ul style="list-style-type: none"> <li>• <i>'... I think I was glad to see someone else... mmm... outside looking in who could see what I am doing and how many tablets I am taking we are talking about two, four, six to eight ten a day so...'</i> 16</li> </ul> <p>Seven said they were previously aware two saying that they had shared their experiences with the group, two were aware of it felt it may be relevant to them but were resistant to decreasing their medication as they felt they needed to take that amount of painkillers to combat their headaches.</p> <ul style="list-style-type: none"> <li>• <i>'...so I'm very aware of it so I try not to take too many but sometimes you just have to because otherwise you just can't function...'</i> 24</li> </ul> <p>One was aware but didn't feel it applied to them. Seven however were unaware of MOH and were either surprised or found it counter intuitive</p> <ul style="list-style-type: none"> <li>• <i>'I didn't realise...'</i> 28.</li> <li>• <i>'I was very sceptical about that I was like no, no that can't be right how can how can something that helps be you know detrimental...'</i> 31.</li> </ul> <p>Four decided to change their medications in light of this information, one came off their medication altogether. One was resistant to changing their medication and two felt this information wasn't relevant to them.</p>
<b>Session 4.</b> Acceptance of chronic headaches	<p>Twelve participants commented on this session.</p> <p>Ten participants found it useful and relevant to living with headaches, <i>'..helps you to think slightly differently about things.'</i> 23</p> <p>Six participants spoke about people being in different phases of acceptance, <i>'...different parts of the acceptance curve...'</i> 25</p>

	<p>Some participants recognised where they felt they were : ‘That’s kind of been me!.....that has stuck with me...’15 or recognised this in others, ‘I’m past the phase of ‘Why me?’’09, I’m definitely at the acceptance stage...’23, different people felt differently...’ 01</p> <p>In most groups participants spoke about having good discussions during this session however two participants felt that a different analogy may have been better. One suggested that using a lay facilitator would have been advantageous as facilitators may come over as telling people that they just have to accept their headache.</p> <p>Three didn’t find this session useful ‘...couldn’t see the point ’17, ‘I found that [acceptance session] bizarre.’.</p>
Relaxation and breathing	<p>Thirteen commented on the relaxation and or CD.</p> <p>Five hadn’t used the CD or relaxation after the course. Three used the CD and were continuing to use some form of relaxation.</p> <p>Two just used their own established form of relaxation or guided visualisation. Three felt that they had no time to fit relaxation into their lives even if they felt it might be useful. Two didn’t feel they needed relaxation as they didn’t feel they were stressed.</p>
<b>Session 5.</b> Impact of thoughts, mood and emotions on headaches	<p>Ten people commented on this session.</p> <p>Six felt it was useful appreciating looking at headaches in a different way.</p> <ul style="list-style-type: none"> <li>• <i>I think because I don’t think of it in that way really... I don’t know how it would probably break the cycle... I don’t know whether it would make any difference but it’s useful to think... try and relax try not to worry about getting a headache because 9 times out of 10 I won’t get a headache so I will be worrying unnecessarily about it... so it is useful so it’s a good thing to try and remember... mmm... you are kind of catastrophizing thinking ‘oh I’m gonna get a migraine’ but mostly I won’t get a migraine. 01</i></li> <li>• <i>... I think it was useful although I’m not sure whether I kind of applied that to myself necessarily you know I have tended to just sort of carry on you know as normal sort of thing and... mmm... but yes I haven’t consciously sat down and thought you know, ‘Can I change something here that you know might just prevent them coming in the future?’09</i></li> <li>• <i>... I thought all of the stuff on the headache cycle and it was really helpful I thought I knew it already but it was... it was important to go through the fact that it’s not just one thing but interconnected to everything else... mmm... it was helpful for people to say what they knew were there kind of things that triggered headaches... things that made things better...25</i></li> </ul> <p>Three people looked at the headache cycle and felt it was easier said than done.</p> <ul style="list-style-type: none"> <li>• <i>There again I can see it and I can see like what the answers are for it so yeah I mean it’s got all the helpful coping strategies at the bottom and we did discuss those and I don’t... well in my own case I don’t think I’m doing anything different I mean... I’m trying to drink more and I try to do the other things but as of overly worrying or getting stressed that’s easier said than done you know what I mean...08</i></li> <li>• <i>That’s more easier said than done as well so yeah again it’s like you know it’s all very well putting it up on a board but trying to do it is another matter isn’t so yeah! 24</i></li> <li>• Three people didn’t feel it was relevant to their headaches.</li> <li>• <i>Yeah I didn’t find that useful... I didn’t feel that was relevant to me... mmm... I can’t remember now... I know I sat there thinking this wouldn’t work for me... maybe for some others but not for me.17</i></li> </ul>
<b>Session 6.</b> Headache cycle and breaking the cycle	<p>All 11 who commented on this session agreed that there was a strong link between mood and headache but only one spoke of the sessions aims and content which they didn’t ‘get’ and felt wasn’t clearly delivered.</p>
<b>Session 7.</b> Unhelpful thinking patterns: recognising and	<p>12 participants commented about this session.</p> <p>Most participants had taken on board the messages of recognising unhelpful thinking patterns and the usefulness of reframing these with regard to their headaches some giving examples of how they had applied these personally. This session promoted a lot of discussion.</p>

finding alternatives	<p>Five said that they had identified with unhelpful thinking, <i>'That's me!... I don't really want that to be me...'</i> 15. Five participants spoke about changing their attitudes and thinking to becoming more positive using the reframing techniques taught. <i>'...trying to be positive rather than negative about your migraines.'</i> 19'. <i>'cos I was letting them manage me...'</i> 28 <i>'that was quite interesting actually it was like actually 'turn your thoughts around and think well what can I do.....is there anything I can do to help myself? So that was really good.'</i> 30</p> <p>Three had heard about this technique before and one of these did not get on with the concept at all. Four had not found it useful; one felt it hadn't been explained well enough, <i>'..I can't contribute anything to this because I don't understand it!''I don't think they went into it thoroughly enough...'</i> 8, three others felt the delivery was poor or patronising, , <i>'...I would suspect it's somebody that hasn't ever suffered from a headache that's done this because unless you've actually got a really bad headache and that it's very easy to say 'oh well just do this' it's like somebody just saying 'oh pull yourself together' you know...'</i> 24</p> <p>One person said that this trigger made them go and see their GP to talk about antidepressants, <i>'Yeah it was really good cos you... we... mmm... we were able to identify things that we were doing and everyone was going 'oh yeah yeah' (laughs) but it was brilliant... mmm... but yeah because yeah you know you do... I do all these things and I think this is what triggered me to go and see the doctor about some anti-depressants to be honest because I looked as this and I thought this isn't healthy... thinking all these things...'</i> 31</p>
DVD	<p>Eleven participants said that they had watched the DVD. Two with a spouse, one with a friend and one with their son.</p> <ul style="list-style-type: none"> <li><i>• Yeah because they don't know how you feeling so for them to watch that with you and then they realise... oh there are things we can do to help you as well but they don't know at first... well watching that with her she's more helpful with me than before it's not that she is helpful but watching that she realised that, 'Oh I'm going through something' so she does help more than before yeah which was really good.</i> 26</li> </ul> <p>They felt it was useful to show it to others and one had lent it to an acquaintance. Five felt the content was personally useful, four felt they already knew about the content and two couldn't remember what was on it.</p> <p>One commented that it may have been more useful to those who were newly diagnosed.</p> <ul style="list-style-type: none"> <li><i>• ... so for me I didn't find that overly beneficial but for somebody I think who hadn't been suffering for long I think they might've found that quite useful...24</i></li> </ul> <p>Four hadn't watched it; 2 due to not having anything to play it on, one due to family distractions and one did not say why.</p>
<b>Day 2 Learning how to adapt and take control of your life with chronic headaches</b>	
<b>Session 10.</b> Identifying barriers to change and exploring problem solving and goal setting	<p>Twelve commented on the goal setting session of the CHES intervention. Four were familiar with setting goals in other contexts such as work or another healthcare programme. Seven said they had found goal setting useful and talked about; increasing their fluid intake (2) decreasing or changing their medication (2) doing mindfulness (1) or increasing their practice, (1) and Improving their bedtime routine to help their sleep quality (1). Three felt that they had achieved their goals and three hadn't one felt it was still a work in progress.</p> <p>Five found goal setting was 'not for them' (2), difficult (2) or anxiety provoking when goals aren't met.</p>
<b>Session 11.</b> Lifestyle factors and impact on headaches	<p>Thirteen people commented across the lifestyle session, stress and anxiety and sleep sessions and overall felt it was useful to raise awareness of how these may affect headaches.</p> <p><i>...to understand what it is you are actually doing and see if there is a link and a connection to the headaches you know. A simple one might be you know if you are drinking a lot and you get headaches well maybe you ought to look at that you know..... one of the things that I recognise you know I wasn't drinking enough water in the day sort of thing so I started to have a plan...09</i></p> <p><i>... you can't concentrate on fixing something if you don't have the means like (inaudible) on the simple case the food itself you would have to buy what you can afford you can't buy what you need...16</i></p>

<b>Session 12.</b> Managing stress and anxiety	<p>Participants seemed to value this session.</p> <ul style="list-style-type: none"> <li><i>...also ...it was nice that it was recognised that stress and emotional stress and things like that were a massive part of it and if you can try and look after yourself a bit in that respect then it's gonna help...31</i></li> </ul> <p>Although participants felt that there was a link between people's stress and headaches doing something about it was difficult for some due to their present circumstances.</p> <ul style="list-style-type: none"> <li><i>...but I do agree that all three of them [stress ,sleep and physical activities] are a good idea but easier said than done perhaps... well I was told it was stress 'cause of my migraines by the neurologist ...[went on to describe upsetting family circumstances]... yeah I agree but cutting down stress how you can do it... I don't think there was maybe enough practical advice on how maybe you could do it...15</i></li> <li><i>I feel that for me to manage stress is quite difficult... mmm... anti-depressants have helped which I take... mmm... but I... sometimes I can't see no way out... my stress is with me all the time because... because of [child] and the situation I'm in! 17</i></li> <li><i>... that to me was like yeah ok you know if we could all change our lifestyle I know we would it's very difficult I mean you know I mean I work from home there's not much more of a lifestyle change I could do..... and I'm now a full time carer for my mum that's very stressful so I can't change my life anymore apart from you know put my mother in a home which is not gonna happen..... I agree you know in principle so when they say lifestyle changes I... it makes me laugh cos I mean you know I think a lot of people would love to make an awful lot of lifestyle changes but I don't think it's quite practical so...24</i></li> </ul> <p>However three participants had considered ways in which they could make changes.</p> <ul style="list-style-type: none"> <li><i>... because my job is a very stressful job and we talk about it and they to me to ask my boss for help (inaudible) which I did and when I asked they did reduce some of the job for me..... there are a lot that I didn't even know that just the tiny little bit of effort or something that you do can reflect on you but I didn't know but with this study I realise that even just going for a walk it can help you reduce it but before I didn't really know that I just become in pain I just need something to calm it down but with this it's not all the time you take... just a simple, simple thing!... 24</i></li> <li><i>Yeah I mean at the time as I said I was sort of... mmm... struggling to sleep... struggling to switch off or waking up at sort of 3am... 4am and like, 'Oh my God it's not that time yet!' but... mmm... I think that's helped me push myself to go to the doctors get on Amitriptyline which I do find now I get a solid eight hours...30</i></li> <li><i>... self-help group with this was that we learnt that actually our headaches are to do with stress and emotional stress and you know... mmm... so you look after yourself in that way do some sort of you know self-care really emotionally and try and reduce your stress is going to help the headaches so it's all combination of that that's sort of improved my headaches because I removed myself from a very, very stressful place and... mmm... I actually took three months off work it was... it was that bad... 31</i></li> </ul>
<b>Session 13.</b> Managing sleep better	<p>For some the information about sleep wasn't relevant as they slept well but it was important for others.</p> <ul style="list-style-type: none"> <li><i>Yeah I think that impacts on so many things, not just headaches I think that's important... so many people have sleep problems... mmm... it probably does trigger mine...01</i></li> <li><i>... some of that was also pressure headache and then sometimes if that didn't go then it would turn into a migraine and that was because of lack of sleep so I was getting the lack of sleep with the... mmm... so due to lack of sleep then that also went onto migraine so yes they are connected... definitely connected so a good management of sleep is definitely a contribution to migraines and that so yes... so yes I would definitely say... when you say about what else can they do on that course... yes sleep...24</i></li> <li><i>... before I don't sleep at all I'm always on my phone I try to calm down that as well which is helping me as well. 26</i></li> </ul> <p>Sometimes contextual circumstances also affected sleep.</p> <ul style="list-style-type: none"> <li><i>It wasn't anything that I didn't know already to be fair but I did... it is very, very difficult because of shift work...31</i></li> </ul>
<b>Session 14.</b> Mindfulness	<p>Seventeen participant gave their opinions about mindfulness.</p>



and relaxation for headaches Taster activity – Mindfulness practice	<p>Three were using mindfulness successfully; One already practised it, one restarted it as CHESS reminded them of it and one commenced it finding it helpful.</p> <p>Eight said that mindfulness was not personally useful; Four because it heightened other symptoms of stress, pain or headache ( due to focussing) and four because they felt that they didn't 'get' was mindfulness was. A couple felt it was a fad or trend at present.</p> <p>Three felt that they used a type of mindfulness informally in their lives; either by being focussed on cross stitch or being 'in the moment'</p> <p>Five said that they hadn't used the CD or tried mindfulness.</p> <p>Four felt they had no time in their lives to try it.</p>
<b>Session 15.</b> Medication management	<p><b>Medication Management</b></p> <p>Ten people talked about this session which was considered to be extremely helpful. Nine spoke about how useful it was to see the range of different medications that there were available for migraine.</p> <ul style="list-style-type: none"> <li>• <i>...I didn't know that they come in different categories and I've actually tried ones in the different categories...17</i></li> <li>• <i>Yeah it was good it was interesting obviously very interesting about the overuse and thing and... mmm... and the other drugs that are available because I've not... I mean I've had migraines for years and no one's ever suggested this before...31</i></li> <li>• <i>It was useful because it sort of gives you an awareness of... of where you are. Like you start off taking a couple of Paracetamol and you work your way up to something that's like the Propranolol it's a Beta Blocker it's you know... so it's useful to see what there is available and there's more available than what you think there is because... I think with going to the GP people tend to be prescribed something and if it doesn't work and I'm guilty of it myself a few times you don't go back because you feel like you are being a nuisance but what... what you... what they are saying is 'well no if it doesn't work come back because there's lots of other options' and that's where I've often gone wrong of thinking well that's the only thing available that hasn't worked no point in going back! 17</i></li> <li>• <i>but also explaining that there are Prophylactics because I think they were a bunch of people... unlucky people in our group who's GP's were completely clueless and they and they hadn't been offered Prophylactics...25</i></li> <li>• <i>I didn't realise there were so many different ones cos obviously I just went on Sumatriptan and stayed on it which I will continue to do so because it works...27</i></li> </ul> <p>Two of these 9 participants used the information given to go and discuss medication with their doctor.</p> <ul style="list-style-type: none"> <li>• <i>That was very helpful for me because... mmm... the... mmm... they've got a... they had a chart with all the... A4 sheet with all the different medications and for what and... mmm... I discussed it with her and she then gave me a group of medications to try and I went to the doctors and we... some of them I'd already tried.....err... because the doctor went back through... because I took the sheet to the doctors and he said oh you've already tried these two... mmm... shall we try this one...19</i></li> <li>• <i>I didn't realise you could actually take medication to prevent headaches coming on which I thought, 'Oh you know this is great maybe I should try this?' so I thought I'll go into the doctors and see if they've had the paperwork through and see if they can just suggest me an alternative you know a preventative or whatever they could suggest really I was happy to try anything...30</i></li> </ul> <p>One person who had tension type headaches realised that they had few alternatives other than paracetamol.</p> <ul style="list-style-type: none"> <li>• <i>Just Paracetamol for me because I mean I don't know if you can take Ibuprofen but I can't take that either! 08</i></li> </ul> <p>Two people wanted more in depth information.</p> <ul style="list-style-type: none"> <li>• <i>... I think I'd've had rather... as I say if there was an expert on the course... maybe a pain management expert or something like that that would've been really useful I would've found that very useful... somebody telling you just more in-depth about different types of painkillers and maybe having a chat ...01</i></li> <li>• <i>That was quite interesting... mmm... and I think they... I think that needed to be expanded a bit more and go into depth a bit more...24</i></li> </ul>

<p><b>Session 16.</b> Relationships and communication with family, carers and friends</p> <p><b>Session 17.</b> Communicating better with Health Professionals</p>	<p><b>Communication</b></p> <p>Only 4 people commented on the first listening exercise in pairs which 3 found enjoyable and one didn't find it relevant.</p> <p>Nine commented on the communicating with health care professional's role play session which was considered to be useful to have in the course. Four found it helpful;</p> <ul style="list-style-type: none"> <li><i>... it probably teaches you that when you go to the doctor you ought to write down what you want to say and perhaps what you want to achieve from it and not waffle on and on because he's gonna like not listen to what you say... you've got to be more direct I think... so I think it teaches you that..... I think it's probably helped with the course because it focusses you as to what to do although I have tried to get a bit more like it recently 'cause I think in the past I've... I've come away and I've not achieved what I wanted. 08</i></li> <li><i>...they were quite useful yeah because I think... yeah I... I... I don't tend to write things down when I go to the GP but actually you should do really but I did think it was useful to think that actually yeah you don't get very long and they don't get very long ... no they don't get very long to make to get to know you and work out what's going on so yeah I think it's worth doing to kind of make you think well how maybe would I do it differently...15</i></li> <li><i>Yeah so that was like the going in with the... with a goal on what you wanted to say to the doctor and what you wanted to get out of that appointment cos sometimes it's quite difficult to you know get across to the doctors... I was finding when I was first going in with my headaches it was like 'well just keep taking Paracetamol' 'well it's not doing anything' you know 'I'm not going to keep taking something that isn't doing anything for me' so it was quite good to actually go in and be like 'right ok doctor I want to be put on a preventative I can't live with my headaches like this' you know for a long period of time I can't keep taking Paracetamol that doesn't work so that was really... really helpful. 30</i></li> </ul> <p>Four felt it was not necessarily personally useful as they has a good relationship with their doctor but felt it wold be useful to keep in the course</p> <ul style="list-style-type: none"> <li><i>... I mean I don't have a problem getting the communication going the way I want it but a lot of people do and it's a confidence thing... mmm... if my doctor was just ignoring me or fobbing me off I wouldn't have it... it wouldn't... it wouldn't happen... mmm... but a lot of people are very sort of... they're like 'oh ok then' and off they go and so it's... it... you've got to take control sometimes! 31</i></li> </ul> <p>One person didn't feel it was useful.</p> <ul style="list-style-type: none"> <li><i>...it doesn't matter how good you are or what you plan to say when you go in if you're not a very forceful person like I'm not who won't force the issue of getting the point across if they're not gonna listen you are not gonna get anywhere... a lot of times they need to learn their 'bedside manner!'17</i></li> </ul>
<p><b>Session 18.</b> Managing setbacks – what to do when things don't go to plan</p>	<p>Scant information given by seven most couldn't remember the session except that it was a rounding off and setbacks are part of life.</p>

### 121 sessions

Interviewees were asked to comment on the 121 sessions, the use of headache diaries, and on the telephone support offered through CHES. The results are presented below.

Seventeen people commented on the 121 sessions. All felt that they had got something out of the session.

*... it was a nice way of sort of tying it all up together... 031*

Ten valued the chance to discuss their medication, three using this discussion as a springboard to see their GP to discuss possible changes.



Six appreciated having their headache classified from their diaries. Ten commented specifically about the headache classification they were given; two said there was some confusion at the time as to whether their headaches were TTH and Migraine. Two felt they had a mix of TTH and Migraine although their classification was given as migraine. Two were surprised at the classification of migraine; one because they had never thought that their headaches were migraine and one that their headaches were all classified as migraines rather than mixed. One felt reassured by being given a classification but another didn't understand why they were classified as chronic migraine saying that they didn't understand the term chronic. One participant wasn't surprised by their classification as it had been identified previously by doctors. Four liked the opportunity to talk about medication overuse headaches. Only four spoke about the goals they set although none had achieved their goals and another commented that they felt that the support for goal setting was inadequate. One felt this session wasn't useful for them as they had had the same conversations with other clinicians already.

Fourteen participants commented about the use of diaries, this included their own and the ones completed for the CHES study.

Some said that they had used a diary before either for themselves to monitor changes or for their clinicians. Two said they had never used one. Most felt that the diaries were useful to identify patterns of headache frequency, duration, medication usage or possible triggers. Seeing these patterns written down made them reflect on their headaches and medication. On viewing the diaries some said they didn't realise they had had that many headaches and that it was easy to lose track just recalling. Sometimes the frequency of medications was underestimated. Possible triggers were useful to ascertain patterns or no patterns. The diaries as a visual aid were reassuring for some especially when they showed improvement or to show them that they would pass as they had got through them in the past. For one participant however the pattern was unrelenting, 'seeing it every single day is depressing'. 'No gaps...no breaks...no rhyme or reason'.

Two commented on the CHES diary layout being too cramped making it difficult to put everything they wanted on to it. Some had used diaries to take to their GPs or consultant in the past and one specifically said that they had taken their diary to the doctor to discuss their headache management which culminated in a change of medication. Two said that they preferred an App rather than a paper diary for convenience.

Thirteen commented on the telephone call support: Seven chose not to have the telephone calls as mostly they felt they didn't need them. Six found it useful as a catch up on how they were doing, 2 that they valued the fact that they weren't 'just left' after finishing the group and 121 contact. Two said they did it for the research but not for themselves.

There were some instances (4) of missed phone calls for different reasons (nurse not phoning at the right time, participant not being able to return a call or phone signal problems).

#### *Suggestions for improvement:*

Fifteen people gave their thoughts about what they would change if the intervention was run again. Six felt that it should remain as it is.

Four felt there should be an increased awareness of; people being unable to attend due to their headaches (1) or work commitments (2) also that some people may be apprehensive about attending a group. (2) Individuals suggested specific additions they would make: Two wanted more time for discussion, two more depth on medication management or mindfulness (perhaps with an extra follow up day). One wanted more info on new medication, research, or techniques. Others wanted more help with stress management, emotional aspects / self-care, positiveness or follow on self-help groups/talks.

When asked if they wanted to remove anything, one didn't think the acceptance session was useful and one wanted less slides. Two people felt one day only would have been personally useful but felt 2 days was reasonable for the course for others.

### 3) Changes attributed to participating in the intervention arm of CHESS reported after the 12 month questionnaire.

The results in this section are a summary of our findings full quotations and more information can be found in Appendix 5.

15 participants contributed to this data seven themes emerged from the data.

- Doing things differently;
- It makes you think;
- New Knowledge;
- Changes in medication;
- Change in attitude;
- Raising awareness;
- No change.

Participants often gave responses in multiple themes but there was an overarching feel within the data that it's not just about the headaches its life in general. Data are summarised here the full list of quotations are provided in Appendix 5.

#### *Doing things differently:*

Seven said there was a change in their headache management which included lifestyle factors or reinforcing good practices such as being hydrated, taking breaks, having regular meals, doing relaxation to help with mood, mindfulness or applying pacing strategies.

*Well I'm trying to do things a bit differently like drinking more and like as I say I'm trying to do things a bit more for myself like going out or like doing the Yoga to try and help the tension you know to see if I can do anything through that so I think they are the two things I'm probably doing that I didn't do before.08*

One spoke about getting additional help to trying to change their unhelpful thinking.

*Well the plan is I suppose going on and continuing with things and as I say I might pluck up courage to phone MIND up and you know get in touch with them at some point... see if that might help it's just... it's... it's like the unhelpful thinking which is one of your sheets in the CHESS study I don't know how to change what I think if it was like a question of being like a migraine sufferer and I could take medication or drink more or do things but when it's... when you're thinking about... trying to change how you think... I know your mind's very powerful but it's easier said than done I think sometimes but everybody else can tell you 'oh you know you shouldn't think like that' but when it's yourself it's hard to change the habits that you've already you know started doing time and time again you know! 08*

#### *It makes you think:*

Four said that the group had 'made them think' allowing a time of reflection.

*... yeah it made me look at things differently... it made realise things about my headaches and about me...31*

#### *New Knowledge:*

Three felt they had acquired new knowledge about medication overuse (2) or headache triggers (2)

*Yeah the course taught me how to identify what was my triggers... so I also make sure I drink plenty and I also make sure I eat regular meals as well.28*

#### *Changes in medication:*

Three people had changed their medications, two with an added preventative giving a decrease in headaches and one by adding a triptan which helped give them some flexibility with the management of severe headaches.

*... well I think it wasn't until you guys kind of you know until I signed up to the CHESS study because I would go to the GP and they'd say 'oh just keep taking Paracetamol' whereas at least I had kind of a backing from... from you guys to say 'actually you've got to give me something more than that' and you put in ideas like the Propanolol's and the fact that there were preventatives for headaches which I didn't know about so that was yeah really helpful.30*

#### *Change in attitude:*

Two spoke (one very vocally) about a change in their attitude towards their headaches which had given them more freedom socially and some had taken on new activities. In order to make changes this person needed to address their depression first.

*also I have changed my attitude and actually it was... I might've got there in the end but that course speeded it up and made me start re-thinking my attitude towards headaches which is really useful..... I think the difference is more towards my attitude towards them rather than the headaches themselves there is a bigger difference in that I try and... I try and not make the assumption that I can't do something because of my headaches but the other positive thing that I've done more recently is that I've joined a gym and now my assumption was I can't go swimming because of the reflection on the water and I can't do the gym because the lights will be bad...15*

*I don't let them control me now like I used to I control them... so I don't seem to lose out much on the social side anymore! ... well normally I like lose like two to three days now I'm only losing like a day. 28*

#### *Raising awareness:*

Four were appreciative of the research in raising the awareness of chronic headaches, perhaps legitimising that they are being heard.

*I am pleased to know that it is being taken seriously within a doctor's kind of environment you know it's not just like... whereas before I could've probably easily felt like doctors just wanted to give you painkillers and get rid of you... I don't quite feel so strongly that they will do that now do you know I do feel like there more being looked into than what we actually give credit for in the background so... it... it is definitely something I do not regret doing... mmm... and if ever in the future I was told that there may be some more options available to try then I would definitely be interested in finding out more about that. 23*

One person had tried an ear piercing which another participant had found helpful.

*... one lady who had really bad migraines she had a piercing in her ear.....yeah and she said that was brilliant they stopped almost overnight so when you're a migraine sufferer you'll try anything so I had that done but unfortunately it's not made any difference to me...17*

#### No change:

Five reported no change in their management or knowledge of headaches after attending the intervention either because they felt they knew it all already or because their headaches didn't interfere with their lives or that it wasn't personally relevant

*... so I quite like the group session in that respect... mmm... but I didn't pick up anything from the... mmm... sort of tutorials if you like because to be honest I've been suffering with them for so long that I knew most of it... mmm... because there's nothing new... there didn't seem to be anything new... mmm... nobody was telling me anything I didn't already know which was a shame cos I thought I might learn something new which... mmm... but no so... but the rest... I thought it was very good and I would still do and go for something else...24*

#### 4) 'Headaches over time' Vignettes at baseline, 4ms and 12ms

14 participants contributed to the longitudinal data about their experiences over the lifetime of the CHES trial. (Baseline, 4m and 12m). Eight of these were from the control arm of the trial (or deemed intention to treat as not exposed to the CHES intervention) (see table 10 below) and there were six from the intervention arm (see table 11 below). The vignettes presented in tables 10 and 11 illustrate the participant's headache journey over the lifetime of the trial. We have, from their data, at each point in time, summarised their current position for this we found that there were four themes, which are:

- Headaches under control - not ruling life
- Able to get on with life despite headaches
- Headaches rule or dominate life
- Headaches out of control

These are broad and do overlap/bleed into each other but do provide an illustration of the participant at that point in time. We can see that the control participants mostly move to being more positive about their headache experiences and two have apparently come to the realisation that they need to take control. (Table 11) In the intervention participants we see a positive change in experience, attributed to CHES, whilst we also see that other factors in life (e.g. family, work) also impact, making it harder for change to have happened. (Table 12)

Table 11. Headaches over time' Vignettes at baseline, 4ms and 12ms (Control participants)

ID	Baseline	4ms	12ms
4	Life severely affected by headaches	Pregnant. Headaches slightly better, less severe eye symptoms. Only able to take paracetamol.	Although headaches worse after the birth now feels 'stable' but would like to find other non drug treatments. Blue or Pink?
6	Doesn't let it impact on their life. (Settled in their management of it rather than ?battling)	Same no change	Same
7	Doesn't stop them from doing things. Able to work around some due to retirement. Headaches better now than when working. Has confidence in management. Settled.	Same	Headaches maybe less frequent needing to take less medication attributes to getting older.
10	Living a smaller life. Unable to plan prioritises work but social life pays for it	Although headaches may be slightly better effects are the same as baseline	The plan is I'm not going to give up... the plan is we keep trying new things... the plan is that every article or anything I see or any treatment... I'm not saying any treatment because people say 'oh you must try my chiropractor you must try my osteopath they're amazing' and it's like I've done all of that...
11	Doesn't stop them from doing things	Feel they are managing headaches better less frequent	Reached a point of acceptance self-efficacy and confidence in managing their headaches.
12	Life governed by headaches. Spends 2/3 days a week in	Getting out more in spite of headaches, managing headaches better. Medication same.	Managing headaches better, taking less medication, feels more positive
14	Unable to plan spoils life when gets them. Severe stops life	Context and severity dictating management. Headaches less severe (pregnant)	Headaches worse uncertainty and stress of new job. Return of severe headaches after giving birth
20	Headaches differ in severity. Dizziness and tinnitus a feature. Bad headaches will stop them from socialising. Manages their headaches from just putting up with them to taking medication (Panadol, paracetamol and preventatives). Indian head massage helps. When bad they will lie down, relax and try and sleep it off. Uses a sound machine to manage tinnitus.	Headaches better Tinnitus still a feature but not as bad. Keeps track of them with a diary, 'rides them out' using medication as necessary. <i>I ride them out basically yeah... ..they're generally not too bad at the moment they seem to be behaving! ... but yeah as far as my headaches are going I'm sticking with the medication and just keep taking the tablets... not a lot else I can do really... but yeah it's what you have to live with ain't it unfortunately!</i>	Attributes decrease in headaches to being on right meds (increased nortriptyline) Also relatively stress free time. <i>They've actually been getting better a lot... lot better... mmm... if you look at my diary... ... no but I'm quite... at the moment I mean they're... they're quite settled and I'm quite happy the way they're settled.</i>

Table 12. Headaches over time' Vignettes at baseline, 4ms and 12ms (intervention participants)

ID	Baseline	4ms	12ms
01	Ok as long as has medication says it doesn't interfere with life (although it does at times )	Nothing's changed in management or medication	<i>I don't think I've got a plan at the moment for doing anything particularly different because it's manageable although it's not particularly pleasant.</i>
08	<i>'It slows you down a bit sometimes and you feel that, 'oh I can't be bothered to do that...I'll leave that to another day'...otherwise I just try and get on with life in general...</i>	Headaches were worse due to neck problems then better after saw physio. Headaches drinks more water takes more 'me time.' Trying mindfulness.	Main change is stress due to family needing support. Everything else the same. Considering getting help with unhelpful thinking.
09	Life affected by headaches, worried when has more headaches or more medication	Optimistic about new preventative tablets	Headaches have decreased bringing increased confidence.... <i>what I'm trying to do now is push all that into the background and not even think about them and not even think, 'Oh will I have a headache!' or you know 'Am I gonna have a headache?' or maybe' I won't do this cos I might get a headache!' ... that is a bit easier you know when you have less headaches anyway ... because there's very few entries this year compared to the last two years it does you know enable me I think to sort of... yeah just try and sort of forget about it and... mmm... just carry on almost you know as normal as though nothing's happening and not trying to manage my life around you know the possibilities that I might have a headache or something like that.</i>
15	Headaches affecting all areas of life severely	Headaches still as bad, mood has been worse, psychiatrist has added an anti-depressant, neurologist has changed triptan due to tiredness.	Mood much improved by addition of an anti-depressant. Looking at ways they can be more in control and do more activities using tools taught at the intervention. Acceptance, unhelpful thinking, altering lifestyle by drinking more water and accepting more social engagements.
17	Headache rules their life but has caring responsibilities which also impact on their QOL	Headaches similar, life similar	Not under control, stressful circumstances worsened looking after relative with learning disabilities. Taking more medication headaches worse.
19	Even though they have regular headaches they doesn't let them stop what they're doing, uses distraction and gets on with their life. Feels they would experience their headaches more if they focussed on it or talked about it.	Similar to baseline.	Adding a triptan has helped them to control their headaches a bit more. <i>I mean because I know it's gonna to be pretty ok after about an hour and then I can go out and if it delays it until the following day I prefer to do that cos you know I can enjoy when I'm going out... so it is... they are better and certainly more manageable and it makes it more flexible if you know what I mean.</i>

## 5) CHESS Phone App data from interviews (post 4m questionnaire)

Themes were grouped into potential facilitators and potential barriers (Some people spoke about multiple themes)

### Facilitators to using the App

- Easy to use (7)
- Reminder prompts (4)
- Use of other diary to complete (2)
- Paper forms used instead (1)
- Difficulties in answering (2)

### Potential barriers to using the App

- Changed phone unable to re-access App (2) (+ 1 who could access)
- Missed weeks of data input (6)
- Tech device issues (4) not on SMART devices (includes person who used paper form above)
- Unaware of App or alternatives (3) /reasons unknown (1)

Twenty six participants spoke about the phone App. Three said they weren't aware of the App, the reasons for this weren't clear. Of the remaining 23 seven found it easy to use and four especially valued the reminder prompt. Two spoke about their thought processes around deciding on a response which at times was difficult due to recall or having to average over a week, however two had referred to other personal diaries which had made responding easier. The technical issues were one of the main barrier to completion. Two could not access the App after changing their phone (although another had managed to do this). One had initial problems setting the App up but went on to use it successfully. Four people had not got SMART phones so one used an iPad, one had uploaded it to a spouses iPad, one had completed the paper version satisfactorily and one didn't realise there was a paper version so no data was collected. The two using iPad found it unsatisfactory as they were more likely to miss the window for completion due to inconvenient timing or not always being on their devices. Six spoke about missing weeks when they hadn't remembered, missed the reminder and was then locked out of the system, one person said after missing a few weeks they just gave up.

## Participant feedback (forms completed after the 2-day sessions)

117 participants completed most of questions 1 to 8 and the results are given in Table 13 below.

Feedback forms were given to intervention participants at the end of Day 2 with a stamped addressed envelope for them to return them to the WCTU.

Quantitative satisfaction questions '*Please use the following scale to indicate your level of satisfaction for the following questions where 0 indicates least satisfaction, and 5 indicates most satisfaction*'.

Table 13. Results from CHESS feedback form satisfaction questions.

	0 Least satisfaction	1	2	3	4	5 Most satisfaction	Total responses
<b>1 The course overall</b>			1	11	55	50	117
<b>2 The facilitators leading the course</b>				7	39	71	117
<b>3 The group discussion process</b>				8	41	67	116
<b>4 The amount of time spent on each topic</b>		2	1	17	42	55	117
<b>5 The relaxation taster session</b>		3	6	17	36	55	117
<b>6 The mindfulness taster session</b>		2	8	18	36	50	94
<b>7 The handouts</b>			1	8	40	68	117
<b>8 The course venue</b>	1	6	2	16	35	56	116

In their responses to the last three questions some gave multiple responses often about different aspects of the group intervention.

**Question 9 What parts of the two day course, if any, did you enjoy or value the most?**

114 participants responded we report the main themes and most cited aspects in each theme (two or less comments in each theme aren't reported). There were three main themes:

- Meeting, sharing and discussion with people who experienced the same condition
  - (N=78). Some enjoyed the support and empathy of the group and others the opportunity to swap their stories as well as their management strategies.

*"The group discussions because it was very helpful talking to other people about their experiences and pick up tips from them also it helps to learn you aren't the only one who suffers and they understand what you are going through."*
- Gaining new knowledge. N=42
  - Some spoke about general information N=10 others specifically about aspects of medication (N=11), about headache types and stages (N=10) and about new management strategies (N=8) about triggers (N=3)
- Component preferences of the intervention. N=34
  - The most valued was relaxation (N=11), Mindfulness (N=7), Listening and communicating sessions (N=6) and Unhelpful thoughts (N=3), Facilitators (N=7)

**Question 10 What parts of the two day course, if any, did you least enjoy or find less valuable?**

55 participants responded. We have only presented the three main themes across the data concerning what was least enjoyable or valuable :

- Timing and pitch of delivery (N=14 ).
  - This included when people felt the days were too long, or too much or too little time was spent on different subjects and more activity rather than sitting for too long in front of a screen. Most were in the context of suggestions to improve it however some wanted more time and some wanted less.
- Venue Environment: ( N=12)
  - Many different things fell into this category including unhelpful lighting, heating, parking, poor ventilation feeling cramped noise levels or looking at a screen.
- Component preferences of the intervention
  - Mindfulness not clear or difficult (N=9), Relaxation unspecified (N=5)

The **Any other comments?** open question was responded to by 75 people. These have been classified into positive comments, negative comments and those which were not applicable to either of these responses.

Out of 75 participants' comments 42 were positive which included praise or thanks for the course or the study and 13 negative mainly to do with relevance and delivery and 20 not applicable.

We only had a response rate of 114/ 336 who attended the group intervention. It is unclear whether the trial participant's satisfaction may have affected whether they returned their forms in the first place. It is also unclear whether those who had a positive or negative experience of the groups were more or less likely to be responders. The data is only from 114 participants so the results should be read in light of this. However we will be using this data alongside other sources of data such as attendance and attrition rates and staff delivery staff interviews which will provide triangulation of the experiences of the group overall.



On the whole the feedback looks as though the intervention was well received although some participants found specific components more or less personally valuable and some would advocate some changes to the content or delivery. (Table 13). GP Feedback forms  
Twenty five practices sent responses. We coded responses as positive negative and neutral (see Table 14).

Table 14. Feedback responses from GP practices who participated in the CHES trial

Feedback questionnaire questions	Positive	Neutral	Negative	Blank /ambiguous
<b>Q1 What were your experiences of treating patients with chronic headache within the CHES trial?</b>	12	10	0	3
<b>Q2 To what extent, if at all, has the CHES trial changed your approach to treating chronic headache?</b>	11 <i>"I use your information sheet with all patients to explain chronic headache + the options to treat"</i>  <i>"I was already doing this, but this formalised my approach so I missed less patients"</i>	12 <i>"No change, reassuring that we are doing standard care"</i> <i>"Little impact."</i>	0	4
<b>Q3 How would you describe your practice's involvement in the CHES trial and would you be happy to be involved in similar trials in the future?</b>	23 <i>"Screened patients at the outset. I would be happy to participate in similar trials."</i>	1 <i>"Satisfactory. No - not active in research for foreseeable future due to physical space capacity problems"</i>	0	1

## Fidelity

### Two-day intervention courses

Forty-two CHES intervention two-day courses were delivered. We found that nine out of the 42 did not have recordings for us to analysis leaving us with 33/42. Our plan was to assess three of the components from each course however there were missing data from some courses thus from the 33 groups which had recordings we were able to analysis 90/99 sessions. Reasons for missing data included technical issues with recorders and facilitators forgetting to switch them on.

Table 15. Adherence and competence scores

Intervention Component	Adherence	Competence
	Median % (IQR)	Median % (IQR)
3: Headache information and mechanisms	0.89 (0.79, 0.89)	0.70 (0.60, 0.80)
4: Acceptance of chronic headaches	1.00 (0.80, 1.00)	0.90 (0.65, 0.95)
5: Impact of thoughts, mood and emotions on headaches	0.90 (0.60, 1.00)	0.60 (0.60, 0.80)
6: Headache cycle and breaking the cycle	1.00 (0.79, 1.00)	0.80 (0.70, 0.80)
7: Unhelpful thinking patterns and finding alternatives	0.75 (0.72, 0.87)	0.85 (0.70, 0.90)
10: Identifying barriers to change and exploring problem solving and goal setting	0.90 (0.70, 0.98)	0.80 (0.75, 1.00)
17: Communicating better with healthcare professionals	1.00 (0.86, 1.00)	0.60 (0.50, 0.80)
18: Managing setbacks	0.63 (0.58, 0.77)	0.75 (0.68, 0.83)
Overall	<b>0.83 (0.67, 1.00)</b>	<b>0.70 (0.50, 0.90)</b>

## Adherence

Overall the CHES intervention appears to have been well delivered with an overall score for adherence of 83% (IQR 0.67, 1.00). Table 15 shows that there were some variations in scores with different components with several achieving 100%. 'Managing setbacks' was the lowest score 63% (IQR 0.58, 0.77) followed by 'Unhelpful thinking patterns and finding alternatives' 75% (IQR 0.72, 0.87).

## Competence

Competence scores exhibited higher levels of variability than the adherence score (see Table 15). The overall score was 70% (IQR 0.50, 0.90). The highest level of competence was for 'Acceptance of chronic headaches' (90%, IQR 0.65, 0.95). Two components scored 60% (Impact of thoughts, mood and emotions on headaches) IQR 0.60, 0.80 and (Communicating better with healthcare professionals) IQR 0.50, 0.80.

## Inter-rater reliability

From the total of 90 sessions 10 (11%) were rated independently by two researchers DE & VN. Interrater reliability was high (80% for adherence scores & 90% for competence scores).

## One-to-one sessions

A check of a random 10% sample (27) of the case report forms completed as part of the one-to-one sessions found that overall the sessions were fully completed as required by the protocol with participants being provided with the appropriate information and support as outlined in the CHES protocol.

## Summary

We are pleased to report that we have achieved the primary objectives of the process evaluation. This report is the initial presentation of the results of the process evaluation as we predefined. Here we provide a summary for the findings and as such our discussion here will be limited as it will be looked at again and updated once the study effectiveness results are released.

## Implementation

### Reach & Context

We have strong evidence that the CHES trial was made available across diverse contexts both rural and suburban. As such the trial team were able to reach out to a diverse population in both ethnic mix and from areas with high levels of deprivation. Recruiting from GP practices provided us with a good sample of 31,020 patients from 164 practices representing around 2% of the patient population. Whilst this was consistent what our data do not tell us is if our search strategy captured all of those who may have benefited.

### Recruitment

Whilst it appears that recruitment was very straightforward and successful there were challenges. We recruited a diverse population. Of the 31,020 patients who were contacted, 2178 (7.02%) were interested with 1034 (47.47%) of these meeting the eligibility criteria. A total of 706 (68.28%) were recruited (plus an addition 30 recruited by self-referral). Whilst the study was set up to capture ALL chronic headaches it has become apparent that our population is primarily those who identified, at the time of consent, as having migraine. A predominate theme from our 85 participant sample of those who didn't want to join the study said their 'headache not bad enough' we are unable to say if these may have had a proportion of TTHs. We are unable to assess if this intervention would be suitable for TTH ( only 9 in the whole study) One in our interviewees (id 08) felt excluded in some aspects of the group as everyone was talking about migraines.

It is also important here to note the challenges of recruiting to the interview study as this helps to give an insight into the complex nature of life for those who live with chronic headaches.

### Dose Delivered

43 of the two-day group sessions were successfully delivered. Venues were varied but all were in close proximity to recruiting practices.

### Dose Received

The pre-defined dose for adherence was set at attendance at day one and engaging in the 1-2-1 session with the nurse only, 69% of the participants achieved this. We feel in retrospect that this predefined minimum dose may have been a little low (based on data from the interviews). Whilst day one is very much about information giving day two is about learning to manage your headaches, missing out on this information/learning may have an impact on the effectiveness of the intervention. It is also somewhat concerning that 24% of participants were not exposed to the intervention at all (did not attend sessions or 1-2-1). Participants talked about reasons for absence related to their health and work and family commitments. These are things that also emerged from the participant interviews and may need to be considered in any future implementation of the CHES intervention.

## Early implementation

### Experiences of participating in the trial

Below we draw together data from across the process evaluation bring it together under four broad headings.

### *1. Meeting, sharing with others. Sharing information, reducing isolation.*

Meeting with others to share information was highly valued by group participants. People with advanced levels of knowledge about headaches often found the group confirmed what they already knew but their experience was usually positive about meeting and discussing with others. Some people felt that the intervention may have been better for those who were perhaps early in their headache trajectory. Levels of knowledge and numbers differed group by group, low numbers meant that discussions may have been more limited as pointed out by one of our interviewees who would've liked to be in a larger group for this reason. An interactive session on where to find 'up to date' reliable info for now and the future may have been useful to all for reference, helping people at all levels. This would also tap into research out there and more cutting edge treatments being tried which was included in the feasibility but taken out. At the time it was considered not to be 'first line accessible treatment' and was difficult for 'non-experts' to deliver. Lay facilitation was part of the feasibility study and had to be changed due to practical logistic reasons. One interviewee commented that the acceptance session may have been better delivered by someone who had experience of headache. Two people spoke about how they had shared (hopefully helpfully) their experiences of coming off their medication to assess if medication overuse was contributing to their headaches in the past. This was sometimes a difficult message to deliver and receive. Instances were given of poor facilitation where messages weren't clear or the tone of the session could have been better. Lay input may have helped with this. This was echoed by the facilitators and from our fidelity findings.

### *2. Time paradox/ Busy lives but valuing the space/Attendance*

Participants valued the opportunity to discuss and explore their headaches and it gave them a space to focus on how they managed them. For some it confirmed or reassured them that they were already optimising their treatment, others felt that they had picked up new information such as MOH or different ways of management. However often it was difficult for people to carve out time to attend the groups due to their busy lives. We know that migraine studies in the past have reported attendance problem due to the nature of unpredictable migraines.

### *3. Technology*

A DVD and 2 CD's were given for personal use. Some people didn't have the means to play these. A download of these was also available but as someone pointed out still kept them tied to a device. Technological advances mean that at the inception of CHESS DVD's and CDs may have been more widely used and therefore more acceptable. Phone Apps were not as widely used. CHESS also developed a phone App for collecting regular data on frequency, duration and intensity of headache. For those who used it qualitative work suggested it was easy to use for most the main issues; not being able to reconnect easily with a new phone or forgetting to complete it - if busy or not having the device to hand (e.g. when on an iPad). (Paper copies of phone App questions were provided for those without a smartphone).

### *4. Did CHESS change people's headache management?*

Evidence from our intervention case study vignettes and additional interview data from participants at 12 months do appear to show a trend towards improvement in living with their headache. However the data have revealed that chronic headaches are very complex and how people live with and manage them is equally as complex.

## **Fidelity**

Considerable effort went into looking closely at the fidelity of the 2-day intervention. The evidence shows that the intervention was competently delivered and adherence to the script was also very good. We can from this feel that, for those who were exposed to the intervention, that it was delivered as planned. In addition to data from the fidelity checks we have data from participants and facilitators that highlight some

areas where changes could be made to the programme. These are outlined within the recommendations below.

## Implementation

### What are the barriers and facilitators to trial implementation?

- Barriers:
  - Not reaching all headache types – study mainly migraine (which in itself is not a barrier but CHES was for all headaches).
  - Attrition rates / drop out / adherence
    - Possibly due to the complexity of life with chronic headache – working, family, coping.
  - Difficulty in contacting participants.
    - Whilst it has looked easy in terms of the numbers recruited and participating maintaining contact with participants has proved challenging throughout.
  - Whilst the two day course was overall well liked there were issues from both the participants and facilitators about a number of the sessions included.
- Facilitators:
  - Those who did attend, and may have been reluctant beforehand, found that it was a valuable and they are glad that they attended;
  - High satisfaction with the intervention from those who attended showing that some participants gained new knowledge and some had changed their headache medication or management.

## Mechanisms of Impact

### Effectiveness

From our data we are unable to pinpoint any specific groups who may have benefitted but:

#### Contextually:

- External stresses impacted on headaches and people's ability to manage their headaches.
- London participants were more difficult to contact and are underrepresented in the interview study.
- Three control interviewees from baseline became pregnant which altered their headache management. KS the trial coordinator mentioned about pregnancy to the CI MU when inputting CRF data.
- The feel from the team was that these people were busy with many commitments. Did we reach enough who were working?

On the whole the CHES study was well received by participants, facilitators, and GPs (see feedback). Participants enjoyed interacting with others. Some gained new information on medication or its overuse and some facilitators at the focus group felt there was a trend to reduce the amount of medication they were taking, not necessarily to stop altogether. Some had added or changed medications, some with good effect. Some used the different techniques or advice such as lifestyle changes including, sleep, exercise and relaxation. However there were those who already knew the information and some did not wish to change how they managed their headaches.

It was not a case of one intervention aspect or technique being most helpful but participants finding what worked for them. This suggests that different sessions may have been helpful or not helpful to individuals. Some people's headaches changed, others found they could manage them better, some decided not to

make any changes and some decided to alter medications after discussions with their doctor. GP feedback comments showed that the study gave an opportunity for participants to discuss the medical management of their headaches.

This intervention also gave a safe, knowledgeable space for people to explore their CHs. Participants valued this opportunity to talk, share and discuss their headache experiences with others in a similar situation. Many mentioned that they do not talk to others often about their headaches and often only see the doctor when their headaches are unbearable. Two people said that they would 'tag their headaches on to another consultation' which may indicate that they themselves don't consider headaches to be a legitimate reason to consult their GP especially if they feel that there is nothing more that can be done.

## Future

*Is the CHESS intervention generalizable, scalable and deliverable in the NHS? What are the experiences of the providers of the intervention and its perceived impact? (PE Objective)*

Potential changes to Intervention if rolled out:

- Improved facilitator training in facilitation and confidence in delivering the material
- Some lay input (real or virtual) – the need for some empathy (someone who has been there...).

Package of 2 days and a 121 sessions work. The days could be shorter by:

- Take out relaxation and mindfulness taster and signpost to how they could access free tasters to try and bring experiences back to the group.
- Take out managing setbacks on Day 2, (this worked better when had 3 days but didn't work as well on Day 2)
- Make medication session more information giving (discussions weren't as helpful and were more likely to go off track).

Add: Practical searching session to reputable sites to get latest information / breakthroughs / new things on the market, NICE guidelines for current practice and medications available and forums for support.

Signpost to: Other alternative therapies they could try and how to access them.

Perhaps including an information table with localised sources included.

This would have the effect of making them expert patients involved in their own care which hopefully will enhance discussions with their GPs about their future care based upon the best information available.

This is a small population so groups may sit better across CCGs to include enough people to populate groups.

## Limitations

Almost all of the participants felt that this research was important and were extremely thankful that someone wanted to research CHs. Some felt this gave some legitimisation of having frequent headaches. However these are participants who agreed to be in the study. There may be an element of desirability bias telling the researcher what they wanted to hear although probes were used at interview to ask for any changes they would make to the intervention as stated in the results. We also do not know if this intervention helps those with TTH as we only interviewed one person with this classification and there were only nine TTH participants in the whole study. However the process evaluation did capture the experiences of being on the study for those participants with migraine and medication overuse headaches.

## Recommendations

It was our aim to perhaps be able to identify contexts in which it may be worth exploring (e.g. sub-group analyses). Our data presented here indicates that it may be worth looking at those participants who were fully exposed to the intervention compared to those who were not. The rationale is that day one, of the intervention, is very much about information giving whilst day two is about learning to self manage and the 1-2-1 consultations are there to reinforce this. Not being exposed to these parts of the intervention may have a negative impact on the person's ability to bring about change.

The following recommendations are based on, or have emerged from, our analysis of this process evaluation data and our immersion within it. The majority are suggestions for any future implementation of CHES.

- The inclusion of Lay input especially with difficult message sessions (during 2-day course) (Could be virtual or pre-recorded).
- Increased training for staff
  - In facilitation techniques (e.g. getting over difficult messages).
  - Building confidence – mock delivery.
- Helping participants to become more expert and recognise their existing expertise in how they research and manage their headaches.
  - Reference booklet – local groups, reputable forums, NICE guidelines
- Recruitment and adherence
  - It seems that not everyone who lives with a chronic headache is accessible from GP records therefore we suggest that more inclusive strategies are used (e.g. social media and advertising)
  - Look carefully at when and how the intervention is delivered (e.g. venues, timings, lighting, furniture etc.)
- Technology (things change quickly)
  - Be up to date and easily accessible for the majority of the desired population, realistically convenient with alternatives if necessary.

## REFERENCES

1. **The International Classification of Headache Disorders** [<https://www.ichd-3.org/>]
2. Stovner L, Hagen K, Jensen R, Katsarava Z, Lipton R, Scher A, Steiner T, Zwart JA: **The global burden of headache: a documentation of headache prevalence and disability worldwide.** *Cephalalgia* 2007, **27**(3):193-210.
3. Karikari TK, Charway-Felli A, Høglund K, Blennow K, Zetterberg H: **Commentary: Global, regional, and national burden of neurological disorders during 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015.** *Front Neurol* 2018, **9**:201.
4. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D *et al*: **Process evaluation of complex interventions: Medical Research Council guidance.** *BMJ* 2015, **350**:h1258.
5. Oakley A, Strange V, Bonell C, Allen E, Stephenson J, Team RS: **Process evaluation in randomised controlled trials of complex interventions.** *BMJ* 2006, **332**(7538):413-416.
6. Demment MM, Graham ML, Olson CM: **How an Online Intervention to Prevent Excessive Gestational Weight Gain Is Used and by Whom: A Randomized Controlled Process Evaluation.** *Journal of Medical Internet Research* 2014, **16**(8):1-1.
7. Ellard DR, Taylor SJ, Parsons S, Thorogood M: **The OPERA trial: a protocol for the process evaluation of a randomised trial of an exercise intervention for older people in residential and nursing accommodation.** *Trials* 2011, **12**:28.
8. Gotlib Conn L, McKenzie M, Pearsall EA, McLeod RS: **Successful implementation of an enhanced recovery after surgery programme for elective colorectal surgery: a process evaluation of champions' experiences.** *Implement Sci* 2015, **10**:99.
9. Oakley A, Strange V, Stephenson J, Forrest S, Monteiro H: **Evaluating Processes: A Case Study of a Randomized Controlled Trial of Sex Education.** 2004, **10**(4):440-462.
10. Partridge SR, Allman-Farinelli M, McGeechan K, Balestracci K, Wong ATY, Hebden L, Harris MF, Bauman A, Phongsavan P: **Process evaluation of TXT2BfiT: a multi-component mHealth randomised controlled trial to prevent weight gain in young adults.** *The International Journal of Behavioral Nutrition and Physical Activity* 2016, **13**:7.
11. Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D *et al*: **Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance.** In. London: MRC; 2014.
12. Steckler A, Linnan L (eds.): **Process Evaluation for Public Health Interventions and Research.** San Francisco: Jossey-Bass; 2002.
13. Nichols VP, Ellard DR, Griffiths FE, Underwood M, Taylor SJ, Patel S: **The CHES trial: protocol for the process evaluation of a randomised trial of an education and self-management intervention for people with chronic headache.** *Trials* 2019, **20**(1):323.
14. **English indices of deprivation 2010: research report** [[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/6871/1871208.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/6871/1871208.pdf)]



## APPENDIX

### Appendix 1. Reasons provided for non attendances at group sessions and nurse one-to-one sessions

Tables #1& 2

#### Midlands

Reasons	Before group started	At Day1	At Day2	121
Work	9	3	1	
Unwell	8	3	3	1
Family/friend commitments	4	2	2	1
Migraines	0	4	3	
No reason	6	6	3	2
Unable to contact		3		1
Forgot		3		
Withdrew	1		1	
Car trouble	1			
On holiday	1			
Too busy	1	1		
Changed mind	1		1	
Trial processes		4		
Travel			1	
Other commitments	1			

#### London

Reasons	Reasons for not attending before and on day 1 (data not broken down)	2 <sup>nd</sup> group offered	3 <sup>rd</sup> group offered	At Day 2	Reasons for not attending 121
Work	6	1		2	
Unwell	3	2		3	
Family/friends Commitments	1			1	
Migraines/headaches	2	1		1	
No reason	12	5	2	12	
Unable to contact	2		1		4
Forgot				1	
Withdrew	2	1		1	
Mix-ups or misunderstandings	1	1		3	
Moving abroad		1			
Other commitments	1				
No money/bad nights				1	

## Appendix 2. Usual care and Relaxation Arm interview analysis

### Relevant methods

Of the baseline interviewees (21) one control participant withdrew from the trial for unrelated health reasons, and 4 who were allocated to the intervention arm didn't attend the groups and were analysed as Intention to treat. This is data is from nine participants plus two intention to treat participants (the other two of these participants declined a 2<sup>nd</sup> interview - one due to health reasons and one said they were too busy)

### Relaxation CD

Some didn't use the relaxation CD either because; they didn't have a CD player (2), they didn't think it would help them personally (2)

*...but I haven't actually listened to it because I don't have a DVD player...14*

*I don't generally use CD's players but also I don't feel that tension is a major part of my headaches so I didn't really believe that it would help me as well. 07*

*.....I had a funny idea that it wasn't going to work...12*

or that they used alternative relaxation apps which they preferred (1). (This participant's preferred relaxation was a 'quick and easy' application on a wristband unit).

*...but I have been using... mmm... it's on the Fitbit it's a breath App so it's relaxation and breathing exercise App 02*

Two preferred a phone App for its portability, one had used other relaxation phone Apps and one of these managed to get the CHESS application to play on a mobile (this was not a usual route of administration in the study).

*... I don't generally play CD's... mmm... if I want to listen to music or whatever I'll probably do it on my iPhone or television...07*

*We tried to do it but I couldn't... I couldn't download it!.....but no we couldn't do it so the only way we could actually do it was to get it on my phone.....sorry... it's easier for me to do it actually because it means I can... wherever I go...20*

Contextual issues were raised by 4 participants mainly to do with not having the time to devote to relaxation in their lives generally or when other life events had taken priority e.g. a relative's illness or looking after a toddler.

*but it's finding two days a week... 17 minutes when you've got other things going on...20*

*I don't really have time to be honest because you have to have the time out to sit there to be able to listen to it whereas I've got a little one [3yr old]...04*

One tried the CD but found it made their headaches worse from using it during a headache because of the noise and abandoned it when it didn't help and they couldn't find the time to use it regularly.

*...listening to it made me feel worse because it was a noise that was irritating more than anything...*

*...whereas when I have headaches the silence is like a godsend! 04*

Two used the CD, one twice a week and the other for a few months and found the relaxation helpful.

*...so me listening to the voice as she is speaking like the way she's telling me to calm... relax my mind and don't think about anybody else just listen to her voice and it calms me down and it really, really helps me...*

*...but at the same time I am able to help my mum 'cause I now have the information about my headaches I am able to tell her this is what you need to do... 'cause my mum listens to the CD's with me as well.....05*

*... it can often send me to sleep which is... mmm... you are so relaxed and you are so tired at the end of the day... I probably listen to it a couple of times a week...11*

Three spoke of their expectations of using the CD; 2 felt it was not going to help them at the outset but one was enthusiastic about the possibility of using the CD to help their headaches.

*...if I am not basically a meditating person then what is the point of having that CD... ...so I've not used it... I used it once or twice a few times at the beginning...06*

*... I wanted to do it because I thought it was going to help my headache...20*

One didn't remember receiving a CD or letter (these were resent by the trial team after consultation with the PI)

### Information Letter

Two didn't recall reading any information which came with the CD and one didn't mention it at interview. Those who recalled it felt it was useful either as a reminder of what they already knew making them think about how it may have been personally relevant.

*... it was nice to actually read through... mmm... the latest kind of information about migraines because it's a long time since I was diagnosed since I had any sort of regular visits to the doctor about it and of course things move on... information moves on... mmm... the sort of things that can trigger migraines become more widely known so it was useful to have a sort of... an up to date version of... of what's it's about really... not all of this is relevant to me but I can see that if... mmm... if you are sort of someone who has severe and frequent migraines this information needs to cover every case so it needs to cover sort of you know the sort of headaches that I get these days as well as the other end of the spectrum...07*

*it was really interesting you know.....Some bits I knew and some bits I didn't you know it's like I know they were caused by lack of sleep that's one thing that applies to me...12*

Some felt they had gained new knowledge such as the range of medications which were available or the effect of triggers or sleep.

*...the drug uses and doses and stuff like that it was like yeah ok that's probably something new...07*

*... some of the Beta-blockers and things I didn't know about but yeah..... everything that has been sent out has been really useful...20*

Having this information also served to normalise one participant's headaches and validated the headache experiences for two others.

*well it's made me realise as well that it's obviously very common it's not just... it's obviously quite a normal thing to experience all the migraines and stuff it's not like it's just me or anything... so not that's it's nice to know that other people suffer but it's nice to know that it's not just you...14*

*I didn't know a thing about these headaches and when I received the letter I was able to know myself a bit more about the information... so it helps me because I was able to know more and I was able to explain myself more about what these headaches are for I've had and what triggers them and stuff as well.....so I was able to do research on them and I was specially able to sit down and work through it... mmm... so my family knows about these headaches as well so I don't have to keep repeating myself as to what these headaches are... 05*

*... I found to be honest I found being part of all of this really great I mean I felt like... I mean everything I've read... everything I've received I thought it was amazing... mmm... you know I'm so glad I've done it because it's made me a lot more aware of my migraines... and actually being able to say, 'Oh I've been part of a study.' It's like, 'Oh god you know that is something more serious than we thought.' It was, so that has made me feel better... it's given me more of a confidence to say, 'OK this is horrible. I deal with it'...10*

For those who spoke about medication overuse headaches some felt they already knew about this phenomenon although it wasn't clear how much they understood on giving their explanations of it.

### Suggestions for changes

Four people said they would recommend this approach to others and one wouldn't recommend it to everyone but felt it would be useful for people who were newly diagnosed. Three wanted the CD in a more accessible form such as MP3 to play on a phone, one felt the CD was too long.

*...it was fine although saying about the CD for me I... I was quite lucky because my Mum was able to give me a CD player portable whereas I suppose some people wouldn't have that and maybe if it was able to present in like an MP3 format or something...04*

*... that's a pretty basic question that you need to make sure people have something that they can use because I just don't. I mean I haven't had a CD or anything like that for years!.....Yeah I mean if it had been something like I could've downloaded on my iphone or you know something I don't know... that was linked to YouTube or something like that it would've been easy... a piece of cake but because I don't use things like that... I mean I don't have any CD's you know I don't have anything like that.....I think as well you know technology is so different now isn't it...? 10*

*... I still think it's a little bit long winded...20*

Two would have liked to be able to talk to others about their headache.

*...obviously I know one or two people who do suffer but you don't have... you don't go on about it and you know you don't talk about it every time you see them so an in-depth conversation with other people from different walks of life who... err... you know have different triggers and different remedies and all the rest of it would've been quite an interesting thing... I don't know whether it would've been useful but it would've been an interesting thing to do! 07*

One wanted more individual tailoring of the advice and a choice of background music and different voices on the relaxation CD. No suggestions were made as to how we could improve the information which was well received and contained new information for some and was a refresher for others as a source of up to date information about headaches and its treatment.

#### *Recommendations*

The use of relaxation may have been better received and used by supplying it in different forms for different devices. Exploration of people's expectations and the likelihood of them using the relaxation technique would maximise uptake. Some personal introduction to the information may be needed to assess and discuss its personal relevance. As it stands there seem more barriers than facilitators to using this approach with people who find it hard to incorporate relaxation into their lives and often know a great deal about their headaches already.

### Appendix 3. Table of control component data

ID	CD	Info and headache information
2 Not Used  Tech preference	<u>NU</u> I've not used that CD... <u>Tech preference</u> ...but I have been using... mmm... it's on the <u>Fitbit</u> it's a <u>breath App</u> so it's relaxation and <u>breathing exercise App</u> I've been using... mmm... which does help with... if I'm feeling a bit stressed or a bit anxious... mmm... which you just sit and take five minutes and just use that and it does actually... it does actually help but I've not used the CD that comes with the letter... I don't know where it is!	Not mentioned specifically
4 Used but Made Worse  Contextual	No, I had the CD come through but it wasn't working because it was a noise if that makes sense <u>listening to it UMW made me feel worse because it was a noise that was irritating more than anything...</u> <u>...whereas when I have headaches the silence is like a God send!</u> ...I got sent the CD and it came with some details basically for your headache listen to it and try and relax and that was about it really... it was pretty self-explanatory though when you... when you listen to it... it talks you through it... ...but it just didn't help for me! <u>Int:</u> And did you try using it when you didn't have a headache? <u>CON Res:</u> I don't really have time to be honest because you have to have the time out to sit there to be able to listen to it whereas I've got a little one [3yr old]...	<u>Don't recall</u> I can't... no I haven't got a clue.....it was a long time ago... I remember seeing it... I remember seeing the table... but I can't remember reading it!
6 Not Used Not For Me	NU Mmm... got the CD which is kind of best used as a Frisbee.....it's no use! <u>NFM</u> ... it's kind of like a meditate basically <u>if I am not basically a meditating person then what is the point</u> of having that CD... ...so I've not used it... <u>I used it once or twice a few times at the beginning</u> and then that's it!	<u>Nothing New NN</u> ...it's the stuff I've all read before... I did read through it... ...and I did look at it and stuff like that and it was just... the same sort as before... the stuff I've had before... yeah. <u>New Knowledge Med</u> ... like some of these bits here like <u>the drug uses and doses and stuff like that it was like yeah ok that's probably something new</u> but it was probably not something that I really looked into... I looked at the <u>causes of migraines</u> and the (inaudible) because you've got different forms of migraines obviously with the location and stuff like that so

		it's stuff I've kind of read before at times... <b>the only thing that was probably good about that was the medications side of it!</b>
7 Tech preference Not For Me Contextual	<p><u>Tech Pref</u>...and it didn't do anything.....well I suppose... mmm... I don't generally play CD's... mmm... if I want to listen to music or whatever I'll probably do it on my iPhone or television or whatever so although we have quite a few CD's... mmm... I'm not really one for putting them on or sitting listening to them and so it seemed to me sort of something that I wouldn't normally have done and so I just didn't do it which I know I should've done in some ways but maybe it's... err... useful information to know that if I've actually got to take it out of its cover and allow myself half an hour or whatever it is to listen to it regularly and I know the recommendation is quite regular to see if it helps with... mmm... with relaxing and all the rest of it I know that's the purpose of it... but I suppose two reasons... one is that <b>I don't generally use CD's</b> players but also I don't feel that tension is a major part of my headaches <u>NFM</u> <b>so I didn't really believe that it would help me</b> as well.</p> <p>Int: Yeah... right... mmm... would it have made a difference if we'd given it to you in a different format... or is there a format we could've given it to you that... that would've been more acceptable really?</p> <p>Res: Probably not no... probably not.....I think had... if I seriously believed that my headaches were down to... in a large part to tension or stress then I probably would have felt that it was worth trying but I didn't feel a pressing need to try it... mmm...<u>CON</u> I think my headaches used to be before I finished work and... mmm... and had a sort of quieter time generally from day to day I think a lot of them were tension and <b>maybe at that point it</b> would've... it would've been useful.</p> <p>... so I do think it has a place it <b>just isn't for me!</b></p>	<p>... I did read it at the time... err... and interestingly enough... mmm... <b>it made me think (MMT triggers)</b> that I do sometimes have flashing lights which don't... which can end up as a dull headache but not a severe headache... mmm... and I sort of try... need to try and track down what actually specifically causes that and two or three weeks ago I had two or three sessions of that they were fairly minor and they went off but I couldn't understand why that had happened but then I realised that on those days I'd actually had some mushrooms for breakfast along with a poached egg...</p> <p>... <b>so it reminded me that</b>... that there are the symptoms that I don't normally experience which would be quite useful to sort of think... you know where's that come from and why has that happened now... so yeah it was.. it was... it was nice to actually read through... mmm... the <b>latest kind of information about migraines</b> <u>LI</u> because it's a long time since I was diagnosed since I had any sort of regular visits to the doctor about it and of course things move on... information moves on... mmm... the sort of things that can <b>trigger migraines become more widely known so it was useful to have a sort of... an up to date version</b> of... of what's it's about really.</p> <p>Int: So just off the top of your head was there anything really new to you... you were saying that some of it was a reminder?</p> <p>Res: Yeah I think that probably the... the NK... the variety of things that are available for it</p> <p>... yeah they are talking here about <b>medication overuse headaches</b> have you come across that before?</p> <p>Res: Yeah... mmm... when I was getting them more frequently this was a few years ago... mmm... I was warned not to take more than one of the specific migraine tablets in a day... mmm... and I think I did... I've never taken more than one in a day but I have taken perhaps three days... one each day because they've reoccurred or they didn't disappear and I did... mmm... actually have to have the doctor out one day and he said you can't take any more of these because they are actually causing... the</p>

		<p>third thing is caused by having... mmm... those particular pills for the two previous days... so... mmm... I'm aware that you know that if I did go through a bad bout I would have to see if I could find an alternative because you know to take them too often actually produces the same effect... I don't know how that works but it's weird... but...!</p> <p>Int: So roughly how long ago was that?</p> <p>Res: Probably 15 years ago... 12 to 15 years ago!</p> <p>Int: Oh right so quite a while back... yeah... it's just interesting as to whether people had that information really or not!</p> <p>Res: Yes I did.</p> <p>Well I suppose the way my headaches are now... mmm...R <b>not all of this is relevant</b> to me but I can see that if... mmm... if you are sort of someone who has severe and frequent migraines this information needs to cover every case so it needs to cover sort of you know the sort of headaches that I get these days as well as the other end of the spectrum so I browsed through all this and I could see that there was some medication that I have taken or would take and I don't think I would say that none of it was relevant I think I would say that... mmm... it's useful to have the whole range of information for all the headache types because then you can say well yes that is... that's... that's relevant to me and you know forget the rest but if it's not there and your headache type isn't covered then you'd probably still be curious about you know whatever... whether there's more that you ought to know about...whereas I think it is comprehensive... mmm... and I was quite happy to just realise that I was only... only need part of that information but it was all there should I ever need it... so I am quite happy with that yeah... I thought it was well done.</p>
11 Tech preference Regular user Helpful for headaches	<p><u>Tech pref</u> Your one's a bit cumbersome because one I don't have a C... if I had a CD player it wouldn't be difficult at all but I have to be online to listen to your one.....which is a pain actually I... I haven't found a way to download it... err... that's... that's... err... so it doesn't make it very easy to... to move around and be in places.....I've been abroad a</p>	<p>Didn't remember receiving any information</p>

	<p>lot this month and it was not something that was easy to... err... listen to because I need to be online!</p> <p><u>Regular user</u>... a couple of times a week at home... mmm... late at night... mmm... more than any other time to be honest with you... but like yeah... it always... it don't always <b>but it... it can often send me to sleep which is...</b> mmm... <b>you are so relaxed and you are so tired at the end of the day... I probably listen to it a couple of times a week</b> and no more and it's mixed in with other ones that I might be on the tube and just... err... listen to a different one that's very similar but I did get out of the habit actually and now I am back in the habit... <b>habit I do believe it's very useful for... for... err... relaxation and keeping the stress down and that way your headaches are not... I... I don't feel the headaches are there as much...<u>Helpful</u></b></p>	
<p>12 Used but not helpful Not For Me Expectations</p>	<p>Used but Not helpful...yeah but I couldn't get myself to relax basically it says close your eyes and it makes your migraines just go but it doesn't 'cause my brain just doesn't shut up (inaudible) but I notice that with the relaxation CD it just didn't... because I couldn't get myself to relax you know or my brain to relax to put it bluntly. It just didn't do any good...</p> <p>...I gave it a couple of weeks you know and I tried it... I tried doing it at different times...</p> <p>NFM... so it really didn't work for me but it was worth a try... I gave it a good go.....but it just wouldn't do it!.....I <b>EXP</b><b>had a funny idea that it wasn't going to work because...</b> err... err... I did... err.. about three months ago going to a day centre.....for mental health people and they did a relaxation CD there... they put a CD on and everybody sat in a circle and closed their eyes and all this and when it came through I thought I'll give it a try but it didn't do me any good to try and relax...</p>	<p><u>New and prior Knowledge</u>... yeah I found it alright yeah it was really interesting you know.....Some bits I knew and some bits I didn't you know it's like I know they were caused by lack of sleep that's one thing that applies [<u>Relevance</u>]to me but there are little bits there that are ok you know the drug one the only one I can take is Paracetamol because of the amount of painkillers I'm on for my... for my back.</p> <p><u>Medication Overuse Prior Knowledge</u> - ...yeah because my doctor told me... this was a few years ago... because I said to him 'I get headaches' you know and he <b>started talking to me about medication overuse...</b> that's why I don't take a lot of Paracetamol or Ibuprofen... because there's days I can go by when I don't take them at all... I haven't taken any Paracetamol today... so this is a good day but yeah... also the amount of medication I am taking could be causing the headaches so I know about that...</p>



<p>14</p> <p>Not used</p> <p>Context</p>	<p><u>Not Used/ Context</u>...but I haven't actually listened to it because <b>I don't have a DVD player</b> so that's a bit of a struggle but I can see kind of like that it's like a soothing... like soothing music to try and chill you out a bit so I believe that probably would help but to have the time to sit down and just listen to music as well it's quite... <b>you don't really have time to just sit and listen you are always kind of on the go doing something!</b></p> <p>Int: So is it more the CD or is it more that you don't have time or a combination of the two?</p> <p>Res: A bit of both yeah... so I don't have the DVD player anyway to listen to it or a CD player and I don't... to be fair if I did I would've probably only listened to it a couple of times anyway it's just the times and stuff because you get home from work and you've sort of got to go shopping or make dinner and...</p>	<p>... I remember it briefly... I don't remember... I actually didn't look into it that much... I find it <u>very useful</u> all of the information is... is more useful than not having it isn't it... yeah I think it has helped a lot as well 'cause especially before like the questions and when you know that it's going to be helping other people it makes it worthwhile doesn't it I suppose.</p> <p>Int: So when you said it was helpful how has it been helpful do you think?</p> <p>Res: Mmm...<u>MMT</u> <b>well it's made me realise as well that it's obviously very common it's not just... it's obviously quite a normal thing to experience all the migraines and stuff it's not like it's just me or anything...</b> so not that it's nice to know that other people suffer but it's nice to know that it's not just you...</p> <p>Int: Mmm... so yeah it was just whether you feel you've learnt anything... learnt anything different or new from the study or not?</p> <p>Res: Mmm... <b>no I don't think so</b> not yet...</p>
<p>18</p> <p>20</p> <p>Used</p> <p>Context</p> <p>Expectations</p> <p>Tech devices</p>	<p>No recollection of receiving CD</p> <p><u>CON</u>...as I say the only bit that I can't get to grips with is the relaxation bit of it...</p> <p>...because I just... it's... it's... I kind of find it... I know it's only 17 minutes but it's finding 17 minutes...</p> <p>...I know that sounds a bit stupid...</p> <p>...and I know it only says like try and find two days a week <b>but it's finding two days a week... 17 minutes when you've got other things going on</b> and you are trying to... 'cause it's trying to like I say... see after the dogs because my dogs are stupid and they are trying to bark... bark... bark... bark and sometimes when you are on your own and you are trying to say to the dogs... be quiet and it's trying to like sit quietly without them barking or and it's just... it don't happen so you just give up it's so you just don't do it or... and then you get stressed because you don't do it do you know what I mean?</p> <p><u>CON</u>: ... and then when [husband] got poorly... everything just got put on hold...</p>	<p>No recollection of receiving information</p> <p><u>MO PK</u>...that was a long time ago now... sorry... (pause) oh yeah... yeah because I read yeah because it says about the medication cos... cos that's why I don't use those... cos yeah like I said <b>I know about the medication overuse</b> cos of the Cocodamol and all that ... that's why I try not to use Cocodamol too often.</p> <p>Int: And was that something that you knew before?</p> <p>... yeah that's why I try not to use Cocodamol... cos I've got Cocodamol that I use occasionally...</p> <p><u>NK</u> Mmm... it was... most of it I knew from being a nurse to be honest... mmm... I knew about the... mmm... the... mmm... a lot of opioids and things like that... mmm... <b>some of the Beta-blockers and things I didn't know</b> about but yeah... yeah</p> <p><u>Useful</u>... everything that has been sent out <b>has been really useful</b>... mmm... yeah absolutely... absolutely fine...</p>

	<p>CON : and then when he was poorly I was saying to him 'come and do this with me' and we were both doing it and that was... that was good but... and then I've... yeah it's... I've done a bit and I've left it and I've done it but it's... but it's just not... I haven't done as much as I feel like I should've done or... EXP ...I was really, really excited because I just thought... I thought it was gonna... I wanted to do it because I thought it was going to help my headache and I knew... well that's what I was so... so... I said to [husband] 'Oh my God!' it was I just felt it was going to be a way to... to ease them... mmm... and I was really looking forward to doing it and it has in a way... 'cause I do think it has in a way</p> <p>Tech devices :We tried to do it but I couldn't... I couldn't download it!... ...but no we couldn't do it so the only way we could actually do it was to get it on my phone.....sorry... it's easier for me to do it actually because it means I can... wherever I go... because we go down to [county] a lot it means I can... I've got the phone wherever, I've got it now... yeah it's a lot easier.</p>	
Intention to treat		
05 Used Helpful	<p>They used the CDs (relaxation and mindfulness ) but mainly the relaxation and found them helpful. They also shared them with a parent.</p> <p>I've been using that on my bed when I've had a migraine and... mmm... and I do have a laptop under my pillow anyway I have it next to me (inaudible) and last night I did use it I had my headphones on... mmm... the voice that's there I am listening to that voice and no one else is in the room so I don't tend to be by myself so me listening to the voice as she is speaking like the way she's telling me to calm... relax my mind and don't think about anybody else just listen to her voice and it calms me down and it really, really helps me...</p>	<p>They found information about migraine really useful, especially to give their headaches a classification to validate her experiences as well as seek support from her family.</p> <p>New Knowledge... but I was shocked but at the same time I was relieved 'cause then I was able to know what my headaches were and I was able to research it as well...</p> <p>...I said to [name of trial coordinator (TC)], I spoke to [name of TC] and... mmm... I was saying to her that I've done some research on these headaches so I'm able to know many ways of it helping me because before you know when I met you first in January I didn't know a thing about these headaches and when I received the letter I was able to know myself a bit more about the information 'cause when I told my family about the letter about the headaches, What headaches have you got ? I</p>

	<p>...but at the same time I am able to help my mum 'cause I now have the information about my headaches I am able to tell her this is what you need to do... 'cause my mum listens to the CD's with me as well.....yeah she does the relaxation CD's 'cause I told her about them so she listens to them as well and she's err... it helps her as well relax we are lying in my bed at the same time and we are listening to it and she got that tired (inaudible) she woke up and was like ok I feel a bit better so she felt relaxed as well and they have helped in many ways.</p>	<p>wasn't able to explain to them but now I'm able... they know what headaches I've got now and what I suffer from as well... mmm... so it's helped me because now I've realised... mmm... I've done research on them as well so I am able to you know when they ask me how long do these headaches last and you know why do you get these headaches I am able to explain to them 'cause I've done the research so it helps me because I was able to know more and I was able to explain myself more about what these headaches are for I've had and what triggers them and stuff as well.....so I was able to do research on them and I was specially able to sit down and work through it... mmm... so my family knows about these headaches as well so I don't have to keep repeating myself as to what these headaches are...</p> <p>... but basically they were saying you know you are just an attention seeker .....if you want to take the mick out of me then that's fine with you but I know what's going on in my brain... I know what is going on with my body I know ways to control it and everything I'm just telling you I suffer with migraines, if you can't support me then that's fine..... My family know everything and my auntie that I am close with I showed her the leaflets I basically told her... I go to her, 'look auntie these are my headaches... these what causes them' and you know (inaudible) I need to talk to you and she says, 'yeah that's fine you can speak to me whenever you need to...'</p> <p>...we tend to eat curries and that sort of stuff so that's what triggers them as well like the foods that I eat so I am able to know and to stop eating if the sodium is high and the sugar as well I know what I need to eat... mmm... so it's helped me a lot with the information since I've seen you....</p>
10	<p>No CD player, therefore not used ...so they're you know I mean... yeah it... it... yeah... I mean the only time I have a CD player is in the car but it's not the first thing I'd want to do in the car so I don't have a CD player so... mmm... yeah I haven't used them if I'm honest...</p>	<p>They appreciated the information and having the interviews. Being part of the study also validated their headaches.</p> <p>... I found to be honest I found being part of all of this really great I mean I felt like... I mean everything I've read... everything I've received I thought it was amazing... mmm... you know I'm so glad I've done it because it's made me a lot more aware of my migraines whether that's a good thing or a bad thing...</p>

		<p>... you know to meet you that time and to have you to speak to... and I think what it does... I think migraines... I think they're so isolating because you have... I mean if I work I work and I put on a brave face nobody knew I had a migraine at work last week... so I put on a brave face that in itself is a strain and it is isolating because you're with people... you're in a crowd but you feel like hell...</p> <p>... I think having these one to one's with you is great...</p> <p>...while and actually being able to say, 'Oh I've been part of a study.' It's like, 'Oh god you know that is something more serious than we thought.' It was, so that has made me feel better... it's given me more of a confidence to say, 'OK this is horrible. I deal with it'...</p> <p>... I think what the study has shown me is just to be more aware... mmm... and just actually that they will go.</p>
--	--	---

## Appendix 4. About the group intervention 4ms post randomisation.

### *Would you recommend this course to others?*

Responses from 16/(17) intervention participants interviewed at 4ms showed that all participants said that they would recommend the intervention they received to others for various reasons.

There were seven themes; useful information, meeting/discussing with others, self-management, having the right attitude, a different perspective, overall a good experience and 'not for them.' Some participant's responses crossed multiple themes.

- Nine people said that it had given them useful information either about headaches or what things they could try.
- Six valued meeting and discussing their headaches with other people in a similar situation either to talk or to listen to others about their experiences or to swap ideas. 'In the same boat 'not alone' Shared experience/ lessened isolation.
- Four valued a self-management approach with a range of different things to try.
- Two felt that you needed to right attitude to get the most out of the group.
- Two spoke about learning about themselves giving them a different perspective on their headaches.
- Two just said that it had been good without specifying why.
- Three felt it hadn't necessarily been useful for them but might be useful for others, one of these felt it may have been more useful for people who were newly diagnosed rather than those who were more self-aware or knowledgeable about headaches.

### *Venue*

Ten participants commented on the group venue. Four felt their venue was ok, the others cited a variety of specific issues; Poor ventilation/ temperature control (3), poor parking (2), artificial lights (2), cramped space (2), external noise (1) and poor signage for group (1).

### *Facilitation*

Fourteen people commented on how the facilitators delivered the course.

The majority felt the groups were well run and were positive about the course delivery. Three gave examples of good facilitation techniques used ( 19,30,31)

*...to understand the majority of the time and if you didn't they'd... err... explained very well I thought...19*

*they brought everyone together... made sure everyone had their own input which was good... sometimes you get people that... err... talk and don't talk so it was nice everyone... I think everyone had a good chat and made their points...30*

*...know the two people that were running it were great and they were very accommodating for us because if we went off track they were happy to let us just explore what we were... we were talking about...31*

Four commented on the relaxed environment of the groups.

*... the ladies who lead the course were very good... I think we all felt very relaxed and easy... you know easy to chat...27*

On the whole people valued the opportunity to talk in a group and discuss headaches. *However some people didn't get on with specific aspects relating to the facilitators.*

Three people wanted more expert input into the group one commenting that the facilitators were not experts in headache. Two felt the pace was fine but would have wanted it quicker for themselves. One felt the pace was a bit slow.

Two people didn't gel with one of their facilitators.

*I didn't mind them, I felt more at ease with [name] for some reason than [name] but I couldn't tell you why... mmm... perhaps she was a... I don't know I wouldn't say it was her personality but it's just how you take to somebody telling you something...8*

*... I don't know if I should say this but I didn't feel she was right for it...*

*...she didn't seem to have that... she was a lovely lady... don't get me wrong but she didn't have that empathy with ya... mmm... but she... you know she was lovely and I talked to her and that... mmm... but it would've been nice for somebody to just have a little bit of empathy...17*

Two felt that one of their Facilitators had delivered some sessions poorly where some sessions weren't explained adequately and one where the facilitator just seemed to read from the slides or manual.

*I think somethings perhaps could've been gone through a bit more thoroughly like... it's like how you think about things and all of that... catastrophising and a lot of big words and I thought well... I think I fit into some of these but I don't think they went into it thoroughly enough...8*

*... the way it was executed by the person who was doing the facilitation was a bit muddled up so we didn't fully understand what we were supposed to be doing... mmm... and then she did spend a whole couple of minutes literally reading... through the slides! 25*

The group intervention was well received and when people talked generally about the whole intervention the overwhelmingly prevalent theme in the data was the value they placed on the group experience enabling them to meet with others to share, explore and discuss their headaches.

### *The Group Experience*

Seventeen participants commented about being in a group which almost all found a helpful and positive experience. Five themes were elicited from the data: 1) Discussion and sharing 2) shared experience of headache 3) comparing 4) less isolated and 5) potential alienation. Some talked about multiple themes. Fourteen said they valued discussion and sharing within the group. Contributing to the discussions and listening to others gave them new ideas and coping strategies.

*...and the fact that you know it's interactive and you've got other people and you can talk to other people and you can hear from other people.09*

*Err... there was the overuse of medication wasn't there... that was one of them which I mean I deliberately had... I'd done this with my... with my consultant for two weeks where I had no medication just to make sure that it wasn't causing it so I'd already done that as well... ..but having said that I was able to share that with other people...15*

*... like in general I think it was super helpful to have a group of people who basically suffer about the same things so the levels of kind of sharing and empathy and just understanding and listening were a special thing...25*

*... if someone just teach you and say you don't talk... I don't think you connect that much than if you... then you also have your opinion and all that it does help more than just someone just talking to you and you just listen and we talk as well...26*

Some also felt that other people's experiences helped them to consider things from a different perspective.

*... yeah but other people did things that they did and I thought it was quite useful to kind of share all our own methods of doing things but what works for one does not always work for another... they also... we talked about... mmm... issues we have being at work and how we could resolve them other people do see things from a different perspective well you get stuck in your own little bubble don't you...15*

Eight liked the idea that they were with people in the same boat which gave a feeling of a shared experience of living with headaches and a common purpose for attending.

*Just being able to talk to other people that... that suffered as well... that were suffering as well cos then shared experiences... shared tips... how to control them without the pain... yeah because we all didn't want... we all wanted to come off painkillers we were all fed-up of taking painkillers so any other ideas of how to control was helpful...28*

*...it was nice to see that there was other people that were in the same boat but their situations are completely different as well in their frequency's and their triggers are all different and it was just interesting and at the same time a comfort but obviously it's showing that we are all going through it as well...23*

*Just being able to talk to other people that... that suffered as well... that were suffering as well cos then shared experiences... shared tips... how to control them without the pain... yeah because we all didn't want... we all wanted to come off painkillers we were all fed-up of taking painkillers so any other ideas of how to control was helpful...28*

Eight spoke about comparing themselves to others within the group especially those who felt that their headaches weren't as bad. This made them feel lucky and made them feel more positive about their headaches.

*Some people are obviously even worse with their migraines some people were really ill with them whereas I don't feel if I take medication that I am really ill with it you know . Whereas some people were in bed and unable to do things and rarely I'm like that and that made me feel quite, you know, good. So that was useful.01*

*...I think like anything else with groups... err... you are not the only one suffering in such great... err... amount of migraines you think well surely nobody else can suffer from 20+ migraines a month but there are they're out there and some are worse much worse than me so once you find out somebody's worse than you... you ain't so bad off are you do you know what I mean so it's the positiveness I think of... of that sort of thing and it's... mmm... I mean... and sometimes you... people are quite negative about it and that makes me even more positive to be honest because I... I... I'm dammed if I'm going to get into that! 19*

*... I mean I know there are other people out there that have migraine I suppose I didn't realise there were so many people who took the same medication as me and that it's so widely used and it's reassuring to know that the people taking the medication and how they take it and it was very similar to me...27*

Seven said that attending the group had lessened feelings of isolation, of 'them being the only one.' Finding out there were others in a similar situation was helpful.

*I would say the most useful thing that I found was talking to other people... having people that understand what you are going through... I mean one lady there she actually started crying because she says... she says 'I've never had anybody understand like this nobody's listened to me like this'... 17*

*... the group discussion was actually very good and a lot of people enjoyed that and they came away with a lot more positive thinking because knowing that they are not the only ones out there so you know you go in there and think I am the only one that suffers like this... 24*

Although almost everyone had got something out of the group in terms of meeting with a group of people with similar experiences, there were elements of the group which had the potential to alienated participants. This was mostly due to the personal relevance of the group. Three felt that the group was more for those at work,

*...we did talk about this on the course because I'm retired it affects me differently to the way that course had been planned... err... and presented was more for people who work and what to do for work and understandably you know... if I have a very bad migraine I can stop if you work you can't...19*

*But you see it didn't relate to me that was why... cos these were situ... well sort of almost... I think they were related to work situations and stressful situations that people would find themselves in and how they would work round the situation to relieve their stress so whilst I found them interesting and how the people were suggesting they would deal with them it didn't relate to me because I wasn't in that situation so that was interesting but not useful to me because I wasn't gonna be in that situation! 27*

One that the group was aimed at those who hadn't had headaches for long (who may lack knowledge about headaches), One felt a lot didn't apply to them as they had Tension type headache and there was more information about migraines, this person also felt a bit daunted by the group and didn't understand some of the exercises.

*...but all the other people seemed to have migraine headaches and it seemed... I thought it seemed to focus more on managing migraine headaches than tension headaches you know there was far more information and they were all discussing things like what medication they were one and different things like that and I*

*thought well that doesn't apply to me so I thought a lot of the things like on the paper work that they gave us afterwards you know it says like other resources there were like three migraine things but there was nothing much else for tension headaches...08*

There were some comments about gender issues which again had the potential to alienate people in the group. One male participant said the course was biased towards females another woman felt that women may be uncomfortable talking about hormonal triggers which may make men feel 'out of it.' Men and women may present differently.

*... it was quite a diverse group of people I think... mmm... and... err... it was very biased towards females there was just two men...09*

*... the men and women had sort of different issues a lot of women had the you know the hormone headaches... migraines which was really what mine was.....mmm... I don't know if the women felt a bit embarrassed talking about that in front of men I don't know... mmm... but there were only two men there perhaps a better mix well I suppose that depends on who's on the study there's no men you can't.*

*Int: But you think having... having a better mix male to female would've been better?*

*Res: Mmm... probably for the men I don't know... probably for the men because as... as women we all sort of have similar experiences... mmm... whereas the men they have their experiences like one guy he'd had an accident and he has a lot of pain and his was totally different to ours... mmm... the men might've felt a bit out of it... I don't know. 17*

Only one felt that they got nothing from the group.

*... I didn't get anything off all the other people if you know what I mean... I can understand yeah a group thing is you can all bounce off... well this causes it for me... and this causes... and you can get ideas but it didn't happen in that group...22*

Another felt they had valued the discussion but overall it wasn't helpful as they felt the group facilitators thought that participants didn't know anything when a lot knew a great deal.

*... so I don't think it was that valuable actually... mmm... and I knew the majority of what they were on about because I think it was aimed at somebody who hadn't had migraines or hadn't had headaches for very long... the majority of us there had been suffering for a long time so we more or less... a lot of us knew more or less about it... 24*



## Appendix 5. Changes attributed to participating in the intervention arm of CHESS reported after the 12 month questionnaire.

### *Doing things differently:*

Seven said there was a change in their headache management which included lifestyle factors or reinforcing good practices such as being hydrated, taking breaks, having regular meals, doing relaxation to help with mood, mindfulness or applying pacing strategies.

*Well I'm trying to do things a bit differently like drinking more and like as I say I'm trying to do things a bit more for myself like going out or like doing the Yoga to try and help the tension you know to see if I can do anything through that so I think they are the two things I'm probably doing that I didn't do before.08*

*...the one thing that I would say I have taken away and it kind of resonates and I do think to myself yeah that's exactly me because if I've felt unwell for a few days I will try and cram everything in then as soon as I feel better and I think they said that was probably not a very good thing to do with a migraine so that was helpful definitely! 01*

*... I just wanted to say that's it's been really helpful from the point of view it makes you think about how headaches affect you and what you can do about it... a bit more empowering and there is something I do... do that I didn't do before is that I is I do... err... I try and do a bit of Mindfulness type things... I didn't find the CD's themselves that useful but it made me do my version of it if you know what I mean... I did always listen to music and listen to (inaudible)... but sometimes if you are just sitting you don't have music handy so I occasionally do myself a little body scan...15*

*... I think it's helpful to be aware of that then you are not chasing some kind of silver bullet... mmm... and I think the reminder of you know being responsible for the lifestyle factors... mmm... I think have been... have been really useful...25*

*Yeah I do do the relaxation CD [mindfulness] sometimes but not all the time.....That one I do at the weekend... when I'm free... when I'm at home yeah...26*

*...and just take meself out for a walk or away from people you know and... noise is the worst thing for me if I get a lot of noise and I work in an open plan office so if I'm at work I just take meself out of the office... ...! it's something that the course taught me to do.28*

*... relaxation I've found really helpful that's why I have like my chill out songs and I think it was just sort of coping with your moods so that you try not to let your headaches get the best of you and just try and deal with life the best way you can.30*

One spoke about getting additional help to trying to change their unhelpful thinking.

*Well the plan is I suppose going on and continuing with things and as I say I might pluck up courage to phone MIND up and you know get in touch with them at some point... see if that might help it's just... it's... it's like the unhelpful thinking which is one of your sheets in the CHESS study I don't know how to change what I think if it was like a question of being like a migraine sufferer and I could take medication or drink more or do things but when it's... when you're thinking about... trying to change how you think... I know your mind's very powerful but it's easier said than done I think sometimes but everybody else can tell you 'oh you know you shouldn't think like that' but when it's yourself it's hard to change the habits that you've already you know started doing time and time again you know! 08*

### *It makes you think:*

Four said that the group had 'made them think' allowing a time of reflection.

*I mean I found it quite interesting and I suppose it does make you think about your headaches actually more... 01*

*...when you had the thing about something we did on the course about... mmm... letting you know your headaches sort of ruin the party if you like it made me think, 'Well I've kind of been doing that... I've could've done this... I can't do it... well why not? See if you can' and then decide you can't do it. So I have changed my attitude towards it yeah... and that actually doing exercises has also improved my mood a lot...15*

... well I think I am on balance more actively managing all of those kind of lifestyle factors that can have a negative impact on pain levels and also the... you know... the negative impact on my ability to manage that pain... I was kind of aware of all the different management techniques ahead of time but I think by doing the course last year and being part of the study it kind of keeps reminding me of the fact that I should be doing them and if I do them then it helps also you know doing regular exercise you know staying hydrated maybe try and eat reasonably healthy and kind of regularly... getting enough sleep... all of those things are just kind of being a big cause of the problems about because of the fact that you know I always knew they were helpful stuff you know, it's easier to, you know ignore if life is busy so I think... mmm... I'm just kind of a bit more aware and a little bit more disciplined in you know following up on those things.<sup>25</sup>  
... yeah it made me look at things differently... it made realise things about my headaches and about me...<sup>31</sup>

#### *New Knowledge:*

Three felt they had acquired new knowledge about medication overuse (2) or headache triggers (2)  
... as I said I used to take a lot of medicine for it.....but yeah when I had the study I realised it's not all that good... it's not good for me to be taking that much medicine so I reduced them.<sup>26</sup>  
Yeah the course taught me how to identify what was my triggers... so I also make sure I drink plenty and I also make sure I eat regular meals as well.<sup>28</sup>  
... I understand them more and how to cope with them so thank you very much for letting me come on the study to understand that! <sup>28</sup>

#### *Changes in medication:*

Three people had changed their medications two with an added preventative giving a decrease in headaches and one by adding a triptan which helped give them some flexibility with the management of severe headaches.

...this year is... I only have eight episodes of migraine the year to date which if I compare to last year at the same period 21 and the year before 32 so... mmm... the whole of February I didn't have any episodes and March only one... mmm... and there were some in April and so far none in May so... mmm... yeah it's... that's quite a transformation actually. ...when I saw the doctor and talked about the programme that I'd been on and said 'look here's some other options of medication that were made know to me' etc, etc and she looked at them ... ..and said 'we ought to try the Candesartan' only 8mg tablets... mmm... one a day... err... which is what I've been on religiously ever since ... ..and it's all I can think of that... mmm... you know... that has been responsible for you know the success or the reduction in... in episodes because nothing else has changed nothing either in my life style or... mmm... diet ....<sup>09</sup>

... well I think it wasn't until you guys kind of you know until I signed up to the CHES study because I would to go the GP and they'd say 'oh just keep taking Paracetamol' whereas at least I had kind of a backing from... from you guys to say 'actually you've got to give me something more than that' and you put in ideas like the Propanolol's and the fact that there were preventatives for headaches which I didn't know about so that was yeah really helpful.<sup>30</sup>

... but I found it very useful you know especially the sessions if it hadn't been for the CHES I wouldn't've known about these new tablets[sumatriptan] and those have been I feel very helpful..... it gives me more flexibility if you know what I mean because I know it's gonna to be pretty ok after about an hour and then I can go out and if it delays it until the following day I prefer to do that cos you know I can enjoy when I'm going out... so it is... they are better and certainly more manageable and it makes it more flexible if you know what I mean. <sup>19</sup>

#### *Change in attitude:*

Two spoke (one very vocally) about a change in their attitude towards their headaches which had given them more freedom socially and some had taken on new activities.

... I used to think when I went out for a meal with the family and I didn't feel that great afterwards... you know and we had to... you know kind of a rushed finished I used to think, 'Oh that's my meal spoilt' but now I think, 'At least... at least I went and enjoyed two thirds of it!'and also I have changed my attitude and actually it was... I might've got there in the end but that course speeded it up and made me start re-thinking my attitude towards headaches which is really useful..... I think the difference is more towards my attitude

towards them rather than the headaches themselves there is a bigger difference in that I try and... I try and not make the assumption that I can't do something because of my headaches but the other positive thing that I've done more recently is that I've joined a gym and now my assumption was I can't go swimming because of the reflection on the water and I can't do the gym because the lights will be bad...15  
In order to make changes this person needed to address their depression first.

... I've kind of changed my attitude I think that's because I feel a bit more positive taking the new medication [for depression] as before it was too much effort to try a new thing... ..... the medication change has made me have the energy to try a few more things and then that has the knock on effect of making you feel a bit more positive cos you are able to do a few more things and that's quite good.15  
I don't let them control me now like I used to I control them... so I don't seem to lose out much on the social side anymore! ... well normally I like lose like two to three days now I'm only losing like a day. 28

#### *Research raising awareness:*

Four were appreciative of the research in raising the awareness of chronic headaches.

I am pleased to know that it is being taken seriously within a doctor's kind of environment you know it's not just like... whereas before I could've probably easily felt like doctors just wanted to give you painkillers and get rid of you... I don't quite feel so strongly that they will do that now do you know I do feel like there more being looked into than what we actually give credit for in the background so... it... it is definitely something I do not regret doing... mmm... and if ever in the future I was told that there may be some more options available to try then I would definitely be interested in finding out more about that. 23

you made us feel that we're being listened to and understood and that you know people are taking it seriously and it makes all the difference makes us feel like you know we are being listening to and it is being understood that something is majorly wrong... makes all the difference I think that's the major thing is that we feel that people are understanding that the pain that we're in! 28

... and obviously helpful to realise that there are somethings that I was doing that could've potentially been making it worse so yes it was... it was helpful... ... taking the Paracetamol... mmm... as a sort of... taking it anyway... taking it too often... well not too often but... mmm... taking it every day... ...yeah so I try not to do that now because I remember them saying about the... mmm... medication overuse and I thought that was fascinating so... mmm... I've... err... not been doing that as often and also... mmm... that's help me advise other people as well...31

One person had tried an ear piercing which another participant had found helpful.

... one lady who had really bad migraines she had a piercing in her ear.....yeah and she said that was brilliant they stopped almost overnight so when you're a migraine sufferer you'll try anything so I had that done but unfortunately it's not made any difference to me...17

#### *No change:*

Five reported no change in their management or knowledge of headaches after attending the intervention either because they felt they knew it all already or because their headaches didn't interfere with their lives or that it wasn't personally relevant

... some of it I felt was irrelevant and I couldn't... I failed to see how this... mmm... related to what we were talking about...17

... so I quite like the group session in that respect... mmm... but I didn't pick up anything from the... mmm... sort of tutorials if you like because to be honest I've been suffering with them for so long that I knew most of it... mmm... because there's nothing new... there didn't seem to be anything new... mmm... nobody was telling me anything I didn't already know which was a shame cos I thought I might learn something new which... mmm... but no so... but the rest... I thought it was very good and I would still do and go for something else...24

... mine aren't that bad I mean they're not very pleasant but they don't stop me doing things... mainly because the Sumatriptan does work generally it certainly takes the edge off the pain...27

... because of the fact that they didn't really benefit me in anyway or I didn't feel like they did I've not pursued... continued with them ... because as I mentioned it was helpful to understand other people's issues and to understand other ways of coping and at the same time...23